United States Army Research Institute of Environmental Medicine (USARIEM)

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: Prebiotic and probiotic modulation of the gut microbiota-gut-brain axis during acute stress

Short Title: Prebiotics and probiotics for performance under stress

Principal Investigator: J. Philip Karl, PhD, RD

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

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

RESEARCH SUMMARY	
Informed Consent	It is important that you understand this research study so that you can make an informed decision. This process is called informed consent. • Please ask questions about anything you do not understand. • Feel free to talk with your family, friends, or others before you decide. • After your questions have been answered, you will be asked if you want to participate. If you agree, you will sign this consent form. • You will be given a copy of this form to keep.
Voluntary Participation	You do not have to take part in this research. It is your choice. You can also choose to stop participating at any time during the study.
Purpose	In this study, we want to determine whether supplementing your diet with good bacteria (known as “probiotics”) or nutrients that feed the good bacteria already in your gut (known as “prebiotics”) will help healthy bacteria in your intestines grow, and improve intestinal, cognitive (memory, attention, reaction time, reasoning), emotional, and metabolic responses to physical and mental stress. Results from this study will be used to develop strategies for improving performance under stressful conditions.
Duration	You will be in this study for up to 6 weeks. During that time, you will participate in about 25 total hours of study-related activities.

Procedures	While you are in the study, you will: • **Consume a powder or capsule dietary supplement daily for 28 days.** • **Walk at an incline on a treadmill for 2 hours while carrying 30% or 45% of your body weight** on 3 non-consecutive days. • Participate in 2 separate decision making tests inside a virtual reality dome while wearing a belt that vibrates or delivers electrical shocks to the abdomen when you make an error. • Complete about 80 minutes of computer testing on 3 non-consecutive days. • **Provide blood** (10 samples, ~13 Tablespoons total), **urine, and saliva** samples on 2 non-consecutive days. • **Collect your own poop** 3 separate times using a provided kit. • Complete a maximal exercise test to measure your fitness level. • Follow a **strict, provided** diet during the final week of the study. • **Not be allowed** to drink alcohol during the final week of the study. • **Not be allowed** to use nicotine- or caffeine-containing products during 2 non-consecutive weeks of the study. • **Not be allowed** to take dietary supplements, probiotics or prebiotics for 2 weeks before and during the study or use over-the-counter medications for two non-consecutive 3-day periods.
Risks	The **main** risks from being in this study are: • Muscle fatigue and soreness from exercise. • Bruising and swelling from needles used to draw blood. • Gastrointestinal discomfort (bloating, gas, cramping) from the dietary supplements or provided diet. • Skin irritation, stress or discomfort from the shock device. *Steps that will be taken to minimize these risks are described later in this consent form.*
Benefits	There is no direct benefit to you, but we hope that results from this study will help determine new ways to improve warfighter performance.
Alternatives	The only alternative is to not participate in the study.
Payment	You will be paid for your participation in this study (up to $500 for Active Duty military personnel and federal government employees, and up to $660 for other participants).

COVID Risk Mitigation	Study staff and participants will comply with all COVID-19 risk mitigation procedures in place at USARIEM during the time of data collection. As such, you may be asked to wear facemasks at all times (unless the mask needs to be removed to complete study activities (e.g., eating, saliva collection) and use hand sanitizer 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 activities. You may also be asked to have a COVID test prior to some study activities.

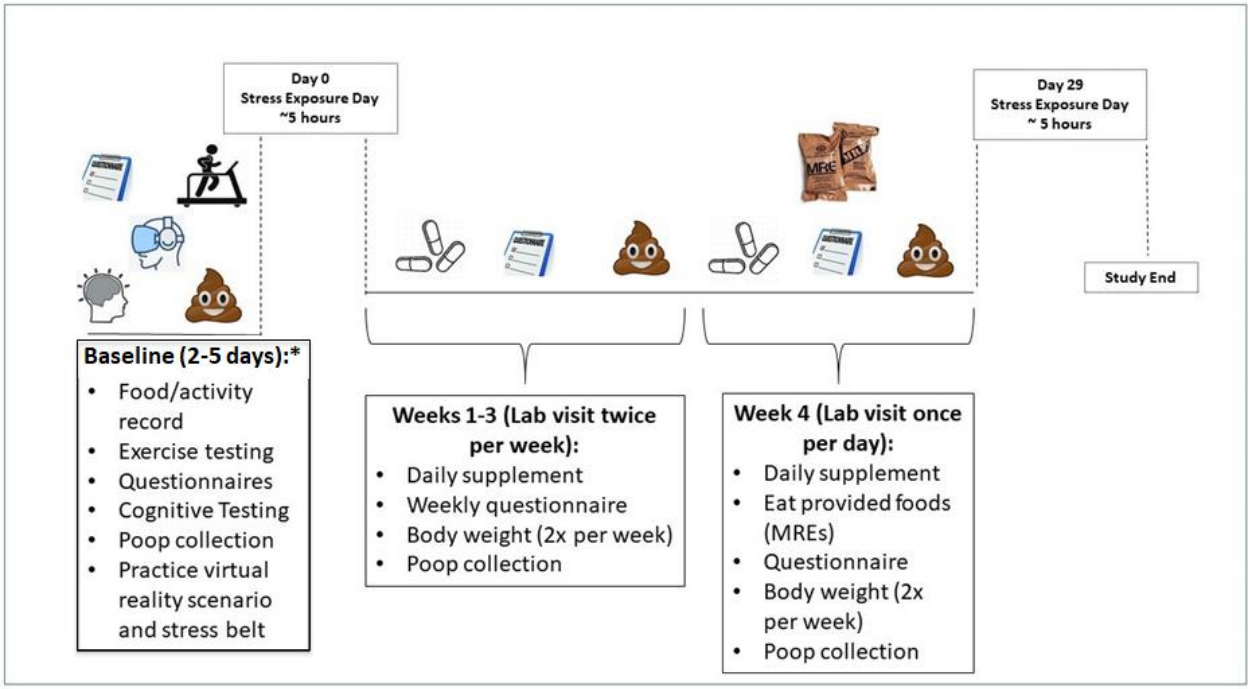
WHY IS THIS RESEARCH BEING DONE?

Warfighters commonly engage in emotionally demanding and physically challenging operations. Recent studies suggest that healthy bacteria in our intestines may favorably influence physical and mental responses under stress. Probiotics are live bacteria, often found in foods such as yogurt, that when consumed can help increase healthy bacteria in our guts. Nutrients in food that "feed" our gut bacteria, known as prebiotics, also help increase healthy bacteria in our guts. In this study, we will determine whether prebiotic and probiotic dietary supplements can improve performance during stress. If successful, these supplements could be recommended to warfighters or added to military rations to help improve military performance.

WHAT WILL HAPPEN DURING THIS RESEARCH?

If you agree to participate in this research, you will be asked to do the following (see Figure 1 and Tables 1 and 2 below).

Figure 1. Overview of the study schedule. All study visits will take place at USARIEM or an alternate location at the Natick Soldiers System Center.



Study screening, orientation and baseline testing

Screening: During screening, you will be asked to fill out a questionnaire which will ask about you (for example, age, race, physical activity) and about the eligibility criteria for participating in the study. After completing the questionnaire, we will also ask you to complete a medical screening with USARIEM medical staff where you will be asked questions about your medical history. Your height and weight will also be measured. If the combination of your weight and height exceed standards set by the Army, you will also have body circumferences measured using a tape measure. For men, the neck and abdomen will be measured. For women, the neck, waist, and hip will be measured. Screening will take place over 1 or 2 visits to USARIEM and will take about 2 hr total. If you pass screening, we will ask you to continue in the study.

Before starting the study, you will be assigned to one of three supplement groups: prebiotic, probiotic, or placebo. The prebiotic and probiotic supplements used in this study are commercially available and safe to consume. The placebo group will take a supplement that looks and tastes like the prebiotic and probiotic supplement, but does not contain prebiotics or probiotics. The assignment will be random and based purely on chance, like flipping a coin. You will have a 1 in 3 chance of being assigned to each group. Neither you nor the study staff will know which supplement you are receiving during the study.

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

Baseline testing (up to 2 weeks): During baseline testing, you will complete several tasks to help you become familiar with the tests that will be performed later during the study. These tasks will include completing questionnaires; a fitness test on a treadmill, a 120 minute treadmill walk while carrying 30% of your body weight on your shoulders/back (you will be asked to carry 45% of your body weight at a slower pace and/or lower incline if you cannot maintain the pace and incline required while carrying 30% body weight), cognitive testing on a tablet computer, calibration of the stress belt device, and practicing the virtual reality decision making test (see Table 2 for details about each task). These tasks will be completed over 2 to 5 lab visits (completed over 1-2wk) that are about 60-180 minutes each. Additionally, we will collect one poop sample from you during baseline.

Day 0: Stress Exposure Test Day

You will complete the first stress exposure test day within 7 days prior to starting Week 1. During the week leading up to stress exposure test days, you will be asked not to use any nicotine or caffeine. The day before testing, you will be asked to drink three liters of water and then provide a urine sample the next morning to be sure that you start testing well hydrated. If you are female, you will also complete a urine pregnancy test. The schedule for the testing day is described in Table 1 below. Testing will take about 5 hours, and will include a 120 minute treadmill walk while carrying 30% of your body weight on your shoulders/back (you will be asked to carry 45% of your body weight at a slower pace and/or lower incline if you cannot maintain the pace and incline required while carrying 30% body weight), a virtual reality decision making test that includes wearing the “stress belt”, cognitive testing on a tablet computer, and questionnaires. You will also drink a beverage containing sugar substitutes and then collect your urine in a provided jug. Additionally, staff will measure your weight, and collect blood and saliva samples from you. See Table 2 for full details of each procedure.

Supplementation phase (Weeks 1-4)

Weeks 1-3: During the first three weeks (days 1-21) of the study, you will be given your assigned supplement to consume daily. You will report to the lab 2 days per week to have your body weight measured, consume the supplement, complete questionnaires, and pick up supplements to take home. On days that you do not visit the lab, a staff member will video call you (via Facetime or similar) to watch you consume the supplement. Each visit/video call will take 15-30 minutes. We will also collect one poop sample from you during Week 3.

Week 4: During Week 4 (days 22-28), you will visit the lab daily to consume your assigned supplement, eat a provided breakfast, have your body weight measured, and pick up your remaining meals and snacks for the day. Meals will consist mostly of Meals, Ready-to-Eat (MRE) rations. During this week you will be asked to not consume alcohol, caffeine or nicotine. Each visit will take ~30 minutes.

Day 29: Stress Exposure Test Day

On Day 29 of the study you will repeat the stress exposure test day. This involves the same procedures and activities as the Day 0 stress exposure test day (see Tables 1 and 2).

Table 1. Testing schedule for stress exposure test day on day 0 and day 29.

Procedure	0 hr		1 hr		2 hr		3 hr		4hr		5hr	
Preparation*	x											
Treadmill walk			■	■	■	■						
Virtual reality testing								■				
Urine collection			■	■	■	■	■	■	■	■		
Blood sample		x		x		x	x		x			
Saliva sample	x	x		x		x	x		x			
Computer testing and/or questionnaires	x	x		x		x	x		x			
Meal											x	
*Preparation includes body weight, hydration status check, and urine pregnancy test (females only).												

Table 2. Description of study procedures.

Procedure	Description	Day
Pregnancy test (females only)	You will collect a urine sample for pregnancy testing. Results will be read to you privately by a staff member. If the result is positive we will not have you participate in the study.	Days 0 and 29
Body weight	We will measure your body weight using a digital scale.	Baseline; Days 0 and 29; Weeks 1-3 (2 times/week); Week 4 (daily)
Food and activity records	You will record everything you eat and drink, and your physical activity for 3 days in a row. This will help us determine how much to feed you during the study.	Baseline

Fitness test	Your fitness level will be determined on a treadmill, while wearing a heart rate monitor and breathing through a rubber face mask or mouthpiece connected to a machine that measures your breathing. The heart rate monitor is held in place using an elastic band that fits around your chest, and tells us how hard your heart is working. You will be asked to run at an incline until you can't run any more. The result will be used to better estimate how fast you need to walk during the treadmill walk. This test takes about 20 minutes.	Baseline
Questionnaires	You will complete questionnaires assessing your mood, emotions, gastrointestinal symptoms and how hard you are working.	Baseline; Days 0 and 29; Weeks 1-4 (1 time/week)
Computer testing	You will be asked to complete several tests on a tablet computer which will measure your cognition (for example, memory, attention, reaction time, and reasoning). You will complete these tests before, during, and after your treadmill walk. These tests will take about 20 minutes to complete.	Baseline; Days 0 and 29 (3 or 4 times per day)
Treadmill walk	You will walk at a moderate pace at an incline on a treadmill for 120 minutes while carrying 30% of your body weight on your shoulders/back. You will also wear a heart rate monitor on your chest and a rubber mouthpiece that is connected to a machine that measures your breathing. If you cannot maintain the pace and incline required while carrying 30% body weight, you will be asked to carry 45% of your body weight at a slower pace and/or lower incline.	Baseline; Days 0 and 29
Virtual reality decision making testing	You will complete a ~30 minute decision making test in a virtual reality dome. This task will measure your decision making under stress. You will practice this task during baseline testing.	Baseline; Days 0 and 29
Stress belt	During the virtual reality testing, you will wear a device on a belt that delivers vibrations (day 0) or electrical shocks (day 29) to the abdomen when you make an error (for example, if you shoot a friend or miss an enemy). This device is designed to cause stress, but will not cause you harm.	Baseline; Days 0 and 29

Urine collection (sugar substitute absorption test)	You will drink water mixed with two types of sugar substitutes commonly used in foods and beverages (sucralose and mannitol). Then we will ask you to collect all the urine you produce over the next 4 hours in a provided jug. The amount of sucralose and mannitol in your urine will be used as a measure of gut leakiness.	Days 0 and 29
Blood samples	We will collect blood from you 10 separate times during the study. Before the first sample is collected you will have a thin, flexible tube inserted into a vein in your arm by a trained study staff member. A blood sample will be collected from this tube 5 times during each stress exposure test day. These samples will be used to measure markers of gut health, inflammation, immunity, stress, and metabolism. We will collect a total of about 190 mL (~13 Tablespoons or ~3/4 cup) of blood from you during the entire study.	Days 0 and 29 (5 samples each day)
Saliva collection	We will collect your saliva 12 separate times during the study by having you place a small sponge under your tongue for about 3 minutes per sponge. This will help us measure your immune function and stress levels.	Days 0 and 29
Poop collection	We will collect 3 total poop samples from you to identify the types and activities of bacteria that are present in your intestines, and to determine how the probiotic and prebiotic supplements influence the growth and activity of these bacteria. You will be given detailed instructions on how to collect a sample and the supplies needed to do it. This may require transporting samples from your home to the laboratory. We will provide supplies for transporting samples.	Baseline; Week 3; Week 4

Additional activities for COVID-19 risk reduction

If COVID-19 risk reduction procedures need to be implemented, we will ask you to do the following:

- **COVID-19 Screening:** At the beginning of each in-person study visit, you will be asked if you are experiencing any COVID-19 related symptoms (for example, fever, cough, etc) and if you have been in contact with anyone diagnosed with COVID-19 within the past 14 days.
- **Temperature checks:** You will have your temperature taken before participating in certain study activities.
- **Masks, distancing and hand washing:** We will ask you to wash your hands or use hand sanitizer during study activities. For most study activities we will also ask you to adhere to local guidelines regarding masking and social distancing.

Additionally, depending on local guidance in place at that time, you may be asked to complete a COVID test at USARIEM the day before stress exposure testing. Throughout the study, if you

test positive for COVID-19, are feeling unwell, have been recently exposed to someone with COVID-19, or if your temperature is >100°F you will not be allowed to participate in study activities on that day. You will be referred for medical screening instead.

HOW LONG WILL I BE IN THE STUDY?

The study will last up to 6 weeks. Study procedures will last between 15 minutes to 5 hours per visit, for a total of about 25 hours of working with study staff during the entire study. However, if the study is interrupted for any reason (e.g., illness, unexpected travel), we may ask you to extend the supplementation period for up to 2 weeks or to repeat baseline tests and day 0 testing. If you decline to extend the supplementation period or to repeat testing you may be removed from study participation.

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:

- During week 4 of the study, you must eat and drink only the foods and beverages that are provided to you and you must not drink any alcohol.
- You must not use any over the counter medications for 72 hours prior to stress exposure days.
- You must not take dietary supplements starting 2 weeks before and throughout the study.
- You must not consume probiotic-containing foods (like yogurt) and foods containing added prebiotics (like inulin) starting 2 weeks before and throughout the study.
- You must not exercise strenuously for 24 hours prior to stress exposure test days.
- You must not consume any caffeine or use any nicotine-containing products (like chewing, smoking, vaping) for a full week before both stress exposure days (a total of two non-consecutive weeks during the study).
- You must not donate blood within 8 weeks of participating in the study or during the study.

HOW MANY PEOPLE WILL BE IN THE STUDY?

We need 54 participant to complete this study. We may enroll up to 216 people to achieve this.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Source of Risk	Risk(s)	How We Will Minimize
Blood Sample collection	Local discomfort, swelling or bruising; dizziness or fainting; nausea vomiting; minor risk of infection	• Only trained and credentialed technicians will draw your blood. • Technicians will use sterile technique.
Exercise	Lightheadedness; muscle discomfort, fatigue, or skeletal strain, sprains; accidental injury	• You will be monitored by study staff during exercise. • Stop exercising if lightheaded. • Exercise restriction the day prior to fitness testing and treadmill walk.

	Cardiovascular risk	You will be screened by medical staff to ensure you are healthy and fit.
Diet supplementation and sudden changes in diet	The probiotic and prebiotic supplements used in the study, and sudden changes to your diet, can cause gas, cramping, bloating, constipation, or other gastrointestinal discomfort	If symptoms are severe we may try to modify your diet or may withdraw you from the study.
Sugar substitutes	Gas, cramping, diarrhea, bloating, or other gastrointestinal discomfort from the sugar substitutes	• Doses used in this study are not likely to have side effects. • You will be asked to report any side effects, and may be removed from study participation if severe.
Stress belt	The shocks delivered by the device will be unpleasant and may be stressful; there is a small risk that the equipment could malfunction and induce a stronger or more frequent shock than planned. The device may also cause minor skin irritation (e.g., redness, marks, burning). If the device is used over multiple consecutive days, there is a very small chance of permanent scarring.	• Device will not be placed directly on the skin. • Devices will be tested before use to ensure proper function. • The device will not be worn on multiple consecutive days.

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?

There are no direct benefits to you for participating in this study. However, results from this study are expected to help warfighters, and other individuals, perform better under stress.

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 the problem. If you have evidence of any physical, mental, and/or medical conditions that would make participating in this study relatively more hazardous, you will not be allowed to participate.

WILL RESEARCH RESULTS BE SHARED WITH ME?

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

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

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

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

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

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

Yes. Volunteers who are active duty military or federal government employees will receive $50 for each successful blood draw, for a total of up to $500 by study completion. If you do not complete the study, you will be compensated for each blood draw you successfully completed.

Civilian volunteers who are not government employees will be compensated up to $660 for completing the study. If the study is not completed, compensation will be prorated based on the study activities completed at the time participation ends. The following payment schedule will be used to prorate compensation for your time: $50 per stress exposure test day completed, $40 for completing baseline and familiarization testing, $20 for completing week 4, and $50 for each successful blood draw.

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

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

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

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

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

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided. No reimbursement is available if you incur medical

expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights. If you believe you have sustained a research-related injury, please contact the principal investigator (PI). If you have any questions, please contact the PI by phone or email (james.p.karl.civ@health.mil).

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

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

Your biological samples (urine, blood, saliva, poop) and/or data will be shared with researchers at the Combat Capabilities Command Soldier Center (DEVCOM-SC); Air Force Research Laboratory (AFRL); Pennington Biomedical Research Center (PBRC); Katholieke Universiteit (KU) Leuven, and Metabolon, Inc. Your biological samples and data will be shared with researchers from those organizations in order to generate and interpret results from the study. Any shared data will be transferred using secure methods. Your biological samples (urine, blood, saliva, poop) will not be used for commercial profit.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity to others. If photographs, videos, or audio-tape recordings of you will be used for educational purposes, your identity will be protected or disguised. If you do not sign a photo release form, any photographs taken of you will be destroyed.

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

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

Once information that personally identifies you is removed from your data or specimens, then your data or specimens may be used for future research studies or given to other researchers for future research studies without your permission to do so. By consenting to participate in this

study you are consenting to allow these samples to be used in future research that may not be directly related to the aims of this study.

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

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of results. You can search this Web site at any time.

WHAT IF I DECIDE NOT TO PARTICIPATE IN THIS RESEARCH?

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

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

If you decide to withdraw, you will be compensated for the portion of the study you completed. The data and samples collected from you will be retained by study investigators and may be used when analyzing the results of this research. If you decide to withdraw from participation, please tell the principal investigator or study coordinator.

WHAT COULD END MY PARTICIPATION IN THE RESEARCH?

The principal investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. This includes if you are unwilling or unable to comply with study procedures (including diets/exercise prescriptions), if you become ill or injured, or if it would not be in your best interest to continue the study. The principal investigator will make the decision and let you know if it is not possible for you to continue. Your taking part in the study may be stopped without your consent if it is determined by the principal investigator that remaining in the study might be dangerous or harmful to you

WHAT IF ANY NEW INFORMATION IS FOUND OUT?

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

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

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

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

Compliance at (508) 206-2371 or by email to usarmy.natick.medcom-usariem.mbx.usariem-rqc-protocol@health.mil.

By signing below, I agree that I have been provided time to read the information describing the research study in this consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

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

SIGNATURE OF RESEARCH PARTICIPANT

Printed Name of Participant

Signature of Participant | Date

CONSENT DISCUSSION CONDUCTED BY:

Printed Name | Date Received