U.S. Army Research Institute of Environmental Medicine

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: Efficacy of a novel exercise + overdressing protocol to induce heat acclimation in temperate environments (Chronic XO-Study)

Principal Investigator: Dr. Benjamin Ryan, Ph.D.

Introduction: You are being asked to participate in this research study because you are representative of an active-duty Soldier and the Army needs to develop practical solutions to prepare Soldiers for hot climates. The study will take place at the U.S. Army Research Institute of Environmental Medicine (USARIEM) in Natick, MA. 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	The goal of the study is to develop a practical way for Soldiers to prepare for hot weather environments. The main purpose of this study is to evaluate if wearing additional layers of clothing (for example, “overdressing”) during exercise in a cooler (68 °F) environment can result in heat acclimation.
Duration	You will be in this study for 16 visits over roughly 8 weeks. Each visit will last approximately 1.5-2 hours (hrs). The entire study is a total of about 29 hrs.
Inclusion Criteria	• Male or female between the age of 18-45 (17 if active-duty military) • Females must be premenopausal. • Body mass index of 18.5-33.0. • Perform aerobic exercise 2x per week and capable of running 2 miles in under 17:00 min • In good health as determined by the Office of Medical Support and Oversight (OMSO) General Medical Clearance.

Exclusion Criteria	• Frequent hot bath or sauna users (e.g., more than three times a week for the past month). • Females who are pregnant or planning to become pregnant during the study. • Taking dietary supplements, prescriptions, or over the counter medication, other than a contraceptive (unless approved by OMSO & principal investigator • Abnormal blood count during OMSO medical screening • Any history of pulmonary, cardiovascular, or renal disease (unless approved by OMSO & principal investigator). • Uncontrolled asthma. • Current or recent respiratory tract or sinus infections (< 2 weeks prior). • History of heat stroke or orthostatic intolerance. • Diagnosed and/or treated for fluid/electrolyte imbalance within the last 30 days. • History of obstructive disease of the gastrointestinal tract including (but not limited to) diverticulosis, diverticulitis and inflammatory bowel disease, peptic ulcer disease, Crohn's disease, ulcerative colitis. • Scheduled MRI during testing. • Allergies to adhesives (e.g., medical tape)
Procedures	While you are in the study, you will: • Complete **2** maximal effort fitness tests • Participant in **4** days of exercise in the heat for up to 60 minutes each day • Participate in **10** days of exercise lasting 90 minutes • Complete a total of **28** fingersticks • Self-insert a temperature pill as a suppository on **14** occasions • Note: Some of the devices used in this study have not been cleared by the Food and Drug Administration (FDA).
Precautions	You will be asked the following before **<u>each of 16 total</u>** study visits: • **NOT** to perform any type of exercise **24 hours** prior • **NOT** to drink any alcohol **24 hours** prior • **NOT** consume caffeine **12 hours** prior • **NOT** to use any nicotine/tobacco product **8 hours** prior • **NOT** to eat any food **2 hours** prior • **DRINK 1 liter (**L) of water • **SLEEP 7 hours** the night prior
Risks	The **main** risks from being in this study are: • Dizziness or exhaustion associated with exercise in the heat or potential musculoskeletal injury from exercise, in general • Dizziness, bruising, or tenderness due to fingersticks • Skin irritation due to medical adhesives

Benefits	The are no benefits to you for participating in this study. The overall benefit of this study is the information gained may lead to the development of exercise strategies that aid Soldiers in preparing for hot environments to reduce the risk of exertional heat injuries and improve physical performance.
Payment	You will be paid for your participation in this study.

WHY IS THIS RESEARCH BEING DONE?

Warfighters must be prepared for advanced military training and operations in hot climates. Heat acclimation, the process of repeatedly exposing oneself to high temperatures, is recommended to reduce the risk of exertional heat injury. However, not all Warfighters are stationed in a hot climate to properly acclimate, presenting a critical barrier in preparation for training or deployment to a hot environment. Therefore, validated heat acclimation strategies for Warfighters stationed in a temperate or cool climate is required.

The purpose of this research is to validate a novel exercise + overdressing strategy aimed at inducing heat acclimation by means of wearing extra clothing layers. These additional layers of clothing are specifically selected to raise body temperature by limiting sweat loss and ensuring heat insulation. The primary purpose is to evaluate if exercise + overdressing performed over five consecutive days can result in heat acclimation. The successful validation of this approach can help develop future heat preparation guidance.

WHAT WILL HAPPEN DURING THIS RESEARCH?

If you agree to participate in this research, you will be asked to do the following:

If you are an active-duty military member or federal civilian employee, you must receive permission to participate in this study from your superior/supervisor. If you are a contractor, you must receive permission from your supervisor/mentor.

You will complete a general and specific medical clearance with the Office of Medical Support & Oversight (OMSO) to determine your eligibility for the study. To complete general clearance, you will be asked to fill out a medical history form, provide a blood and urine sample following an overnight (8-10 h) fast, and complete a basic physical exam. To complete specific clearance, you will be asked to confirm that you meet all of the study inclusion criteria and none of study exclusion criteria described in the briefing. General and specific clearance procedures will take about 2 hours in total to complete.

If you are eligible to participate in this study, you will complete a total of 16 visits. All visits will take place in the morning or afternoon. If a visit takes place later in the day, a snack will be offered, if desired. These 16 visits will consist of the following: 1) two orientation/baseline visits, 2) four visits that will require you to exercise in the heat wearing PTs, and 3) ten visits that will require you to exercise at room temperature wearing either PTs or multiple clothing layers. These ten visits will be split into two blocks, each lasting five consecutive days, and a minimum 4-week break will occur between them.

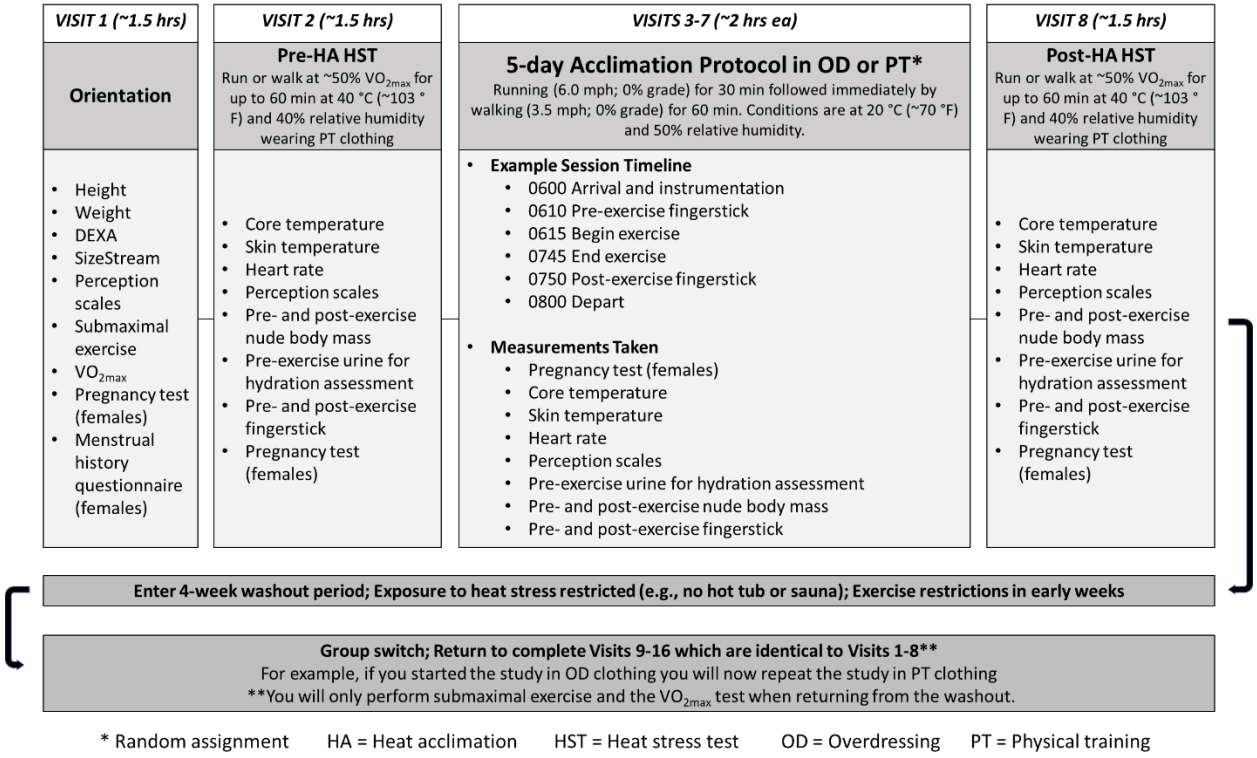

Figure 1. Timeline of Study Visits

Visit 1 and 9

Orientation

Diet, hydration, activity, and sleep standardization: On your first visit to USARIEM, we will provide you with a food log. You will be asked to record what you eat 24 hours prior to each visit so that you may replicate your meals on later visits. You will be instructed to drink an extra 1 L of water the evening before your next trial. You will be instructed to have a 7-hour sleep opportunity prior to your next trials. You will be asked to refrain from using any nicotine/tobacco for 8 hours prior to your next trials, refrain from consuming any caffeine for 12 hours prior to your trials and abstain from any exercise or alcohol consumption for the 24 hours prior to your trials. We will also ask you not to eat any food within 2 hours of each trial.

Age, weight, height, body fat, and body surface area: We will record your age and measure your height and weight behind a privacy screen. We will measure your percent body fat using a DEXA (dual-energy x-ray absorptiometry) machine. For women, you will be asked to provide a urine sample for pregnancy test required prior to the DEXA scan to make sure that you are not pregnant. The results of the pregnancy test will be confirmed and shared with you by a member of the research team. Females will also be asked to fill out a menstrual history questionnaire. Body surface area will be measured using the SizeSteam 3-D Circumference Scanner. This device uses a series of laser sensors to scan the surface of your body. You will be asked to wear form-fitting shorts or pants only (if you do not own or forget to wear form-fitting shorts, then disposable undergarments will be provided by the study staff) only, with the exception of females who in addition will be asked to wear a sports bra and pull hair back in a bun (if possible) for the scan.

Submaximal Exercise: You will perform 10 total minutes of submaximal exercise in either the Overdressing or PT clothing ensemble. Overdressing and PT clothing will be provided for non-military participants to wear during the trials. You will provide running shoes of your choice. You will be either walking and/or jogging on a treadmill while wearing a mask that collects the gases that you breathe out. You will also be fitted with a strap around your chest that measures your heart rate. We will also measure your body mass while wearing both clothing ensembles.

Table I. Overdressing and Standard PT Dress Clothing Ensembles

Overdressing Ensemble
Lightweight Undershirt
Lightweight Drawers
ACU Trousers (or similar)
ACU Blouse (or similar)
Extreme Cold/Wet Weather Jacket (or similar)
Extreme Cold/Wet Weather Trouser (or similar)
Socks
Beanie
Gloves
Running Shoes
Standard PT Dress
PT Shirt
Lightweight Drawers
PT Short
Socks
Running Shoes

Maximal Effort Exercise Test (VO_{2Peak}): Following submaximal exercise, you will perform a maximal effort exercise test on a treadmill wearing PT dress. This test allows us to measure your baseline cardiorespiratory fitness, as well as determine the intensity you will exercise at during testing in the heat.

The treadmill will start at a comfortable running speed that you will self-select. Every 2 minutes the incline of the treadmill will increase while the speed remains the same. The test will end when you can no longer keep up. You will wear the same mask and monitoring strap as you did during submaximal exercise.

On visit 9, once you return from the 4-week break, you will reperform the 10 minutes of submaximal exercise and VO_{2max} test only. The VO_{2max} reassessment is measure any changes in fitness status that may have occurred during the 4-week break. You will not reperform the DEXA or SizeStream 3-D Circumference Scanner.

Visits 2/8/10/16

Standardized Heat Stress Test (HST)

All HSTs will be performed in PT clothing and 72 hrs rest will be provided between each HST and acclimation trial. You will perform these tests before and after your 5-day acclimation visits (Figure 1). You will arrive in the morning with your food log which will be evaluated by study staff. You will be asked to provide a urine sample for hydration assessment. If your hydration is

not adequate, you will be given a 500 mL of water (the size of a normal bottle of water) prior to exercise and your urine will be reassessed for adequate hydration. For females, a pregnancy test will be performed on this same urine sample and you will be provided the result by study staff. Qualified staff will then instruct you on how to self-insert the core temperature pill as a suppository and provide you with the necessary items (lubricant, nitrile glove, MRI safety bracelet). We will then provide you with a privacy screen and so that you can self-record your nude body mass.

Following, we will place skin temperature sensors on your chest, deltoid, thigh, and calf. We will also place a strap around your chest that measures your heart rate. Lastly, we will then perform a fingerstick before you enter the chamber.

The temperature-controlled chamber will be 40 °C, which is about 104 °F, with a slight windspeed. You will exercise on a treadmill at 50% of your VO_{2max} that was measured during the orientation visit. You will exercise for 60 minutes. During exercise, you will be presented with perceptual scales every 10 minutes. You will be allowed to drink a specified amount (200 mL, about half a water bottle) of water every 20 minutes which will be provided to you by study staff. If you need to use the restroom during the trial, exercise will be briefly stopped, and you will be given a urine jug for collection behind a privacy screen. Staff members and other volunteers will not be present while you provide the urine collection. The exercise trial will be considered completed once the full 60 minutes of exercise has elapsed. However, if your internal temperature reaches 39.5 °C, which is about 103 °F, exercise will be stopped immediately and you will be removed from the chamber and cooled with a fan, ice towels, and/or water. Your body temperature will be monitored for 15 minutes, or until it falls below 38.5 °C, which is about 101 °F, whichever occurs first.

Once exercise is over, we will immediately perform another fingerstick. You will then towel off excess sweat and provide a nude body mass behind a privacy screen. We will then remove the skin temperature sensors and heart strap. You will be asked to provide a post-exercise urine sample in the restroom. If you feel that you cannot provide a urine sample, you do not have to, but you will be asked to try again during future visits.

Visits 3-7 and 11-15

<u>Acclimation Visits in Overdressing or PT Clothing</u>

You will be required to perform five consecutive visits in both the Overdressing or PT clothing. The order in which you start will be randomly assigned (Figure 1).

You will arrive in the morning with your food log which will be evaluated by study staff. You will be asked to provide a urine sample for hydration assessment. For females, a pregnancy test will be performed on this same urine sample and you will be provided the result by study staff. Qualified staff will then instruct you on how to self-insert the core temperature pill as a suppository and provide you with the necessary items (lubricant, nitrile glove, MRI safety bracelet). Lastly, we will provide you with a privacy screen and so that you can self-record your nude body mass.

Following, we will place skin temperature sensors on your chest, deltoid, thigh, and calf. We will also place a strap around your chest that measures your heart rate. You will then put on the overdressing or standard PT Clothing ensemble (Figure II). Once you are fully instrumented and

wearing your clothing ensemble, your body mass will be recorded. Lastly, we will perform a fingerstick before you begin exercise.

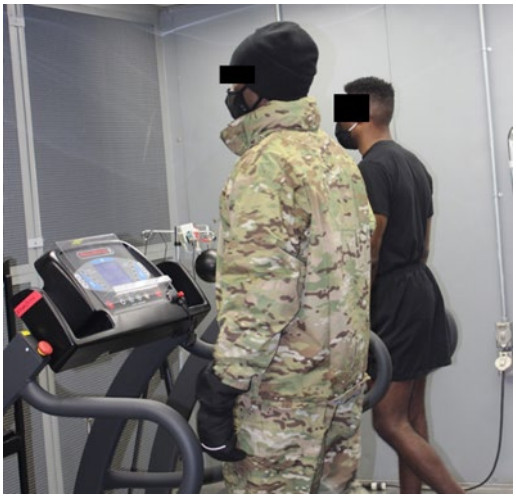

Figure 2. Example of the Overdressing vs. PT Clothing ensembles

Next, you will perform 90 minutes of exercise in a temperature-controlled chamber that will be held at room-temperature (about 68 °F; Figure 2). For 30 minutes, you will run at 6.0 mph and 0% grade. After, you will walk at 3.5 mph at 0% grade for 60 minutes. You will be allowed to drink a standardized volume of water (200 mL) every 30 minutes which we will be supplied by study staff. You will be asked how hot you are and how hard you are working every 15 minutes during exercise. Your internal body temperature will be continuously measured and monitored throughout exercise. If you need to use the restroom during the trial, exercise will be briefly stopped, and you will be given a urine jug for collection behind a privacy screen. Staff members and other volunteers will not be present while you provide the urine collection. The exercise trial will be considered completed once the full 90 minutes of exercise has elapsed. However, if your internal temperature reaches 39.5 °C, which is about 103 °F, exercise will stop and any additional clothing you may be wearing will be removed. Your body temperature will be monitored for 15 minutes, or until it falls below 38.5 °C, which is about 101 °F, whichever occurs first.

Once exercise is completed, we will immediately perform a fingerstick. Then, your body mass in clothing will be weighed and recorded, followed by a nude body mass that you will self-report. Study staff will assist in removing the temperature sensors and chest monitoring strap from you. Before you leave the lab, you will be given a urine cup so that you may provide a urine sample upon arrival during your next visit. You will also be instructed to replicate your food intake prior to your next visit.

No genetic tests will be performed in this study on your blood or urine specimens.

HOW LONG WILL I BE IN THE STUDY?

The study will consist of a total of 16 visits over the course of about 8 weeks. If all visitations are completed, the total duration of study is approximately 29 hrs.

WHAT PRECAUTIONS DO I NEED TO TAKE?

- Not exercise or drink alcohol 24 hours prior to each visit
- Not drink caffeine or energy drinks 12 hours prior to each visit
- Not smoke or use any nicotine products 8 hours prior to each visit
- Not eat 2 hours prior to each visit
- Drink an extra 1L of water the evening before each visit
- Receive a full 7-hours of sleep before each visit

HOW MANY PEOPLE WILL BE IN THE STUDY?

We will enroll up to 24 participants for this study. Complete data from a total of 12 men or women are needed to finish the study. Once all trials are completed by 12 participants, there will be no further volunteer requirement and data collection will end.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Below is a list of potential risks and discomforts from being in this study. Study procedures may involve risks to the participant (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.

Source of Risk	Risk(s)	How We Will Minimize
Heat Exposure	• Heat illness (signs and symptoms include: high core temperature, hot skin, dizziness, nausea/vomiting, etc.) • Hyperthermic risk to fetus	• You can stop exercise at any time if needed • Pregnancy tests will be administered to female participants to prevent exposure of a developing fetus to high body temperature • We will stop testing if your core temperature goes higher than 103°F or if you experience disorientation • Rapid cooling if signs of heat exhaustion are present • Post-exercise monitoring for at least 15 minutes or wait until core temperature falls below 101°F.
Core Temperature Pill	• Slight and brief discomfort during insertion • Not compatible with MRI • Injury to mucous membranes	• Instruction and lube provided for self-insertion • Bracelet provided to prevent MRI while pill is inside body • Screening for obstructive diseases of the GI.
Adhesives	• Skin irritation • Allergic reaction	• Excluded if you have an allergy to adhesive • Skin is properly cleaned and monitored
DEXA	• Low dose radiation	• Dose is 1/3 the radiation from chest X-ray, 1/500 of normal

		annual background radiation, or 1/6 of what you get on a transatlantic flight • Quality check before use • Pregnant women excluded • Scans only performed by credentialed staff member •
Heart Rate Monitor	• Skin irritation • Chaffing	• Medical staff is available on site to provide treatment for skin irritation
Capillary Puncture (Fingerstick)	• Pain, skin irritation • Dizziness, fainting • Bruising • Infection	• Performed by trained staff members • Proper and sterile techniques used
SizeStream Scan	• Potential eye damage from laser	• You will be asked to keep your eyes closed for the duration of the scan
Study exercise	• Cardiovascular risk • Musculoskeletal injury	• Screen for contraindications before exercise • CPR-certified study staff will be monitoring you throughout testing • Medical staff is available to treat you in the event of an injury • 24 hrs or more between trials to allow for recovery and rest

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?

There are no benefits to you for participating in this study. The overall benefit of this study is the information gained may lead to the development of new countermeasures that help Soldiers prepare for deployment to hot climates and reduce the risk of exertional heat injury.

WHAT IF UNEXPECTED INFORMATION IS LEARNED ABOUT MY HEALTH?

There is potential for unexpected health information to be found from your medical clearance and screening for this study, and from DEXA scans conducted during the study that may provide information leading to a medical concern. If any health issue is found, the principal investigator will direct the participant to see OMSO (HRV/military) or their primary care physician (civilian). No diagnoses will be made by study personnel; therefore, the findings will not be reported to health providers. However, you may be encouraged to see your provider or physician if any potential concerns are uncovered.

WILL RESEARCH RESULTS BE SHARED WITH ME?

If you would like a copy of your DEXA (body composition) results, VO_{2max} (maximal fitness) results, or a copy of the final report when the study is complete, please contact Dr. Benjamin Ryan at 508-206-2408 or benjamin.j.ryan14.mil@health.mil for a copy.

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

The only alternative to participating in the research is to not participate in the study.

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

There are no anticipated costs for this study. If you do not reside on the Natick Soldier Systems Center, you will be responsible for your travel costs to and from the base.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

If you are an Active-duty military member or federal civilian participant, you will receive $50.00 per fingerstick (28 for the study). You will only be compensated for completed fingersticks. If all fingersticks are completed, you will be compensated $1,400. For active-duty military, petition for hazardous duty pay will be submitted, although it is not guaranteed that hazardous duty pay will be received.

If you are a non-federal civilian, you will be compensated $50.00 per fingerstick (28 for the study) and compensated for your time ($30 per hour). If all blood draws and study time are completed, you will receive up to $2,270.

If you withdraw from the study or are withdrawn from the study, your payments will be pro-rated. It may take several weeks after completing the study for you to receive payment. All payments will be sent in the form of direct deposit to your bank account. Your social security number 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 Dr. Benjamin Ryan at 508-206-2408 or benjamin.j.ryan14.mil@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?

To protect your privacy, all of your research-related records will be labeled or "coded" with an assigned research volunteer number that will not include your name or any other form of identifiable information. The master key linking the identification number to you will be kept under lock and key or on a password protected computer in a restricted-access folder only assessable by the PI or study coordinator. Any documents that require your name (e.g., the consent form) will be kept in a locked cabinet separate from any research documents that contain your ID number. The PI and study coordinators are the only people who will be able to match the ID with any of your personal identifying information. Additionally, at the closure of the study, there is no intent for any stored biological samples (e.g., blood/urine) to be used for other/future research and all samples will be promptly destroyed.

When the results of the research are published no information will be included that would reveal the your identity to others. Photographs, videos, or audio-tape recordings of you will only be used, if the you grant permission through the Audio/Visual Image Release form. You will also be asked to grant permission for your name to be included on your photo or video image or in writing connected to your image. If you do not grant permission through the Audio/Visual Image Release, then no photos or other visual recordings will be taken of you. If 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 responsible for review and oversight of human research
- DoD and other Federal offices charged with regulatory oversight of human research
- USARIEM Office of Research Quality & Compliance responsible for ethical conduct of human research at USARIEM.

Once information that personally identifies you is removed from your data, then your data may be used for future research studies or given to other researchers for future research studies without additional permission from you. You will not benefit from the potential future use of data.

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

Complete confidentiality cannot be promised for civilian (both DoD and non-DOD affiliated) participants, as data breaches can occur.

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 current or future relationships with USARIEM, your superiors, or the U.S. Army.

If you decide to withdraw, you may do so by notifying the PI or research staff verbally or in writing. We will still use the data we have collected.

WHAT COULD END MY PARTICIPATION IN THE RESEARCH?

We ask that you follow the directions to the best of your ability. If you are unable to do so, or the researchers feel it is best for you to leave the study, the researchers may end your participation in the study even though you might like to continue.

The researchers may have to withdraw you from the study if you become ill or injured during the research. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate. The investigator will make the decision and let you know if it is not possible for you to continue.

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. Any new information will be given verbally to you over the phone or in person.

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 Dr. Benjamin Ryan. Office phone: 508-206-2408; Cell phone: 719-235-7618. Email: benjamin.j.ryan14.mil@health.mil.

If you believe you may have a research related injury or illness, please immediately contact Dr. Benjamin Ryan at 508-206-2408 (both during and outside of duty hours). If during duty hours, you may also contact the USARIEM Office of Medical Support & Oversight (508-206-2265).

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 USARIEM's Human Protections Director, Dr. Robert Roussel at (508)206-2371 or via email at usarmy.natick.medcom-usariem.mbx.usariem-rqc-protocol@health.mil.

ADDITIONAL OPTIONS:

I would like to be contacted about participation in future research studies at USARIEM.

_____Yes _____No Initial your choice

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