U.S. Army Research Institute of Environmental Medicine

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: The Influence of Race and MitoQ Supplementation on Skin Perfusion in the Cold

Principal Investigator: Billie K. Alba, PhD

Introduction:

You are being asked to participate in this research study because you are healthy and between 18-40 years old (17-40 if military), representative of an active-duty Soldier. 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 main purpose of this study is to see if hand and finger temperatures in the cold are different between racial groups and if a dietary supplement containing antioxidant compounds can help to improve hand and finger temperatures in the cold.
Duration	You will be in this study for about 4-6 weeks.
Procedures	While you are in the study, you will • Ingest a high dose antioxidant supplement called MitoQ for **2** days • Participate in **2 cold air exposures** (41°F; **90** minutes (min) each) • Complete **2 hand cold water immersions** (54°F; **30** min each). • Complete a total of **12** blood draws (about 4/5 cup) • Perform laboratory testing of hand function and dexterity

	• Insertable or ingestible thermometer pill on **4** days.
Precautions	You **will** be asked to: • **Not** exercise or consume caffeine or alcohol **12** hours prior to testing (4 study days total) • **Not** consume food **10** hours prior to testing (4 study days total) • **Not** consume antioxidant-rich foods **48** hours before each testing session
Drugs/Devices	A dietary supplement called MitoQ will be orally administered in this study. The supplement has not been evaluated by the FDA.
Risks	The **main** risks from being in this study are: • Lightheadedness or fainting in response to needles or blood draws • Skin sensitivity to adhesives • Intolerance or discomfort during exposure to cold temperatures • Gastrointestinal discomfort from ingesting the MitoQ supplement • Temperature pill not compatible with MRI
Benefits	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 a countermeasure that protects Soldiers from cold injury and helps them maintain their hand function during cold-weather operations.
Payment	You will be paid for your participation in this study.

WHY IS THIS RESEARCH BEING DONE?

U.S. military personnel operating in cold weather are at risk of developing cold injuries, for example, frostbite. They also often experience a loss of hand function and joint mobility due to a decrease in skin temperatures and blood flow. Cold injuries and poor hand function have severe negative impacts on the ability to perform important military tasks such as digital command and control functions, weapons use, and delivery of medical treatment. Therefore, methods to maintain finger temperatures and hand mobility in cold weather environments are needed.

In addition, the risk of getting a cold injury is higher in the Black population compared to other racial and ethnic groups. Increases in oxidant compounds can cause the blood vessels in the skin to narrow and decrease skin temperature in the cold. However, it is unknown whether the higher risk of cold injury in Black individuals is because of a greater amount of oxidant compounds in the blood vessels. The purpose of this research is to see if an antioxidant supplement called mitoquinone (MitoQ) can help to improve finger skin temperature and hand dexterity in the cold, especially in Black individuals.

WHAT WILL HAPPEN DURING THIS RESEARCH?

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

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 (about 10 hours (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. General and specific clearance procedures will take about 2 hours in total to complete.

If you are eligible, you will participate in the study outlined in Table 1, each study visit is described in more detail below.

Table 1: Timeline of study visits.

Study Day	Visit	Length of Visit
1	Orientation + Familiarization	2 hours
2	Familiarization	1 hour
3	Hand Cold Water Immersion (Treatment #1)	3.5 hours
4	Cold Air Exposure (Treatment #1)	4.5 hours
5	Familiarization	1 hour
6	Hand Cold Water Immersion (Treatment #2)	3.5 hours
7	Cold Air Exposure (Treatment #2)	4.5 hours

Study Visits

1. Orientation:

   Weight, height, body fat, pregnancy, and cold exposure evaluation: We will measure your height and weight and your percent body fat will be measured using a machine called DEXA (dual-energy x-ray absorptiometry). You may opt out of DEXA scan and choose to have your mean skinfold thickness measured instead. We will also measure the volume and dimensions (for example, length and width) of your hand and index finger, image your hand to determine the hand surface area, and measure the pigmentation of your skin.
   You will also complete four brief surveys regarding your race and ethnicity, previous exposure to cold environments, the emotions and stress level that you typically experience, and how you would rank your overall social and economic status. For female participants, we will ask you to also complete a menstrual cycle history questionnaire.

   We will provide you with a diet sheet that you will use to record all the foods and beverages that you eat or drink in a 72-h period to establish you baseline diet.

2. Familiarization Visits

You will practice the dexterity and strength tests about 10 times (over 3 sessions; refer to Table 1 above). We will also have you sit in a thermal chamber (set at 41°F) for approximately 5-10 minutes during the first familiarization session (Day 1) so that you know what it will be like on an experimental day.

3. Experiment trials

You will participate in two experiment trials, one after consuming the MitoQ supplement and another after the placebo (sugar pill that contains no MitoQ). The order in which you receive each treatment will be random and based purely on chance. Neither you nor the research staff (except a staff not involved in data collection) will know whether you are getting the MitoQ or the placebo.

Each experiment trial is consisting of a Hand Cold Water Immersion visit and Cold Air Exposure visit (Table 1). A minimum of 45 hours will occur between testing visits (for example, between Study Days 3 and 4 and between Study Days 6 and 7). A minimum 2-week washout will occur between trials (i.e., between Study Days 4 and 6).

The MitoQ supplement: A commercial nutritional product marketed as an advanced antioxidant that is especially effective at reducing oxidative stress, or “free radicals”, that develop from daily life. MitoQ has not been reviewed or evaluated by the FDA. Although the dose use in the study (80 milligrams (mg)) is eight times the recommended supplemental dose, it is within the range of acute doses safely administered in previous research studies.

Testing Visits: You will be provided a diet log and will be asked to record all food and beverages that you consume the day before each testing session. You will be asked to consume the same types and quantities of food the day prior to each test session.

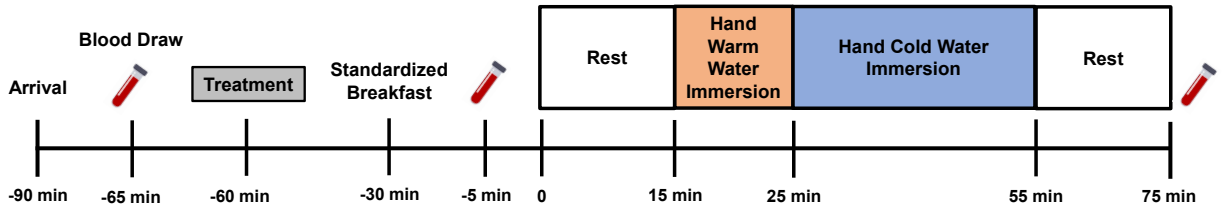
On each testing visit, you will arrive at the laboratory following an overnight (about 10 hours) fast. You will swallow or place as a suppository (self-insert into rectum) a pill to measure your core body temperature. You will ingest a single dose of treatment (4 pills totaling 80 mg MitoQ or 4 placebo pills), and we will give you a standardized breakfast about 30 min later. The experiment will start approximately 60 min after you ingest the treatment. We will draw your blood 3 times, once before you ingest the treatment, once after you ingest the treatment, and once again at the end of the testing session (see pictures below). At the end of each testing day, you will fill out a questionnaire to survey for possible side effects of MitoQ.

Hand Cold Water Immersions

Hand cold water immersions will be performed on Study Days 3 and 6 (once following MitoQ ingestion and once following ingestion of the placebo; see Table 1 above and the figure below). You will be wearing a t-shirt and shorts during the test. The air temperature in the room will be at a warm temperature (81°F) during the whole test.

You will rest (sitting in a chair) for 15 minutes. You will then immerse one hand (covered in waterproof glove or bag) completely in warm 95°F water for 10 minutes. After this you will immediately put the same hand in cold 54°F water for 30 minutes. You will then remove your hand from the water and remain seated for 20 minutes.

We will measure blood pressure, heart rate, core temperature, skin temperature, skin blood flow, thermal comfort and sensation, and pain level throughout the experiment, as described further in the table of study procedures (see Table 2 below).

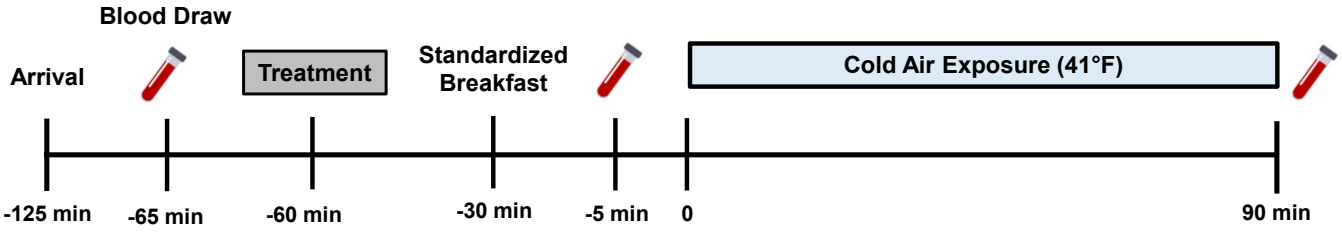


Cold Air Exposures

You will sit in a cold 41°F room for 90 minutes on Study Days 4 and 7 (once following MitoQ ingestion and once following ingestion of the placebo; see Table 1 above and the figure below). You will be wearing a base layer underneath pants and a long-sleeve top during the cold exposure. You will be provided the base layer, pants, and long-sleeve top to wear during the testing visit. You will wear your own undergarments (e.g., underwear, sports bra) underneath the base layer.

You will not be allowed to huddle, close or rub your hands together, or do any physical activity while in the cold room. You will be allowed to use the bathroom only if it is absolutely necessary, but no breaks can otherwise be permitted. In some circumstances, you will be provided a privacy screen and may be asked to urinate in a sterile jug or portable urinal in the cold room. If it is necessary to leave the cold room to use the bathroom, the time spent outside of the cold room will not count towards the 90 min of cold air exposure.

We will measure your blood pressure, heart rate, body temperature, skin temperature, body heat production, thermal comfort and pain level, skin blood flow, and hand dexterity and strength (described further in Table 2 below) throughout the experiment. At the end of the testing, you will fill out a questionnaire to indicate which treatment you think you have received.



Study Procedures

The study procedures and the days on which they will be performed are described in the following table.

Table 2: Description of study procedures.

Procedure	Description	Study Day
Pregnancy Test (Female participants only)	If you are a female, you will self-administer a urine pregnancy test, prior to DEXA scan and at the start of Day 3 & 6. If the result is positive, we will not have you participate in the study.	Days 1, 3, 6
Body Weight and Height	We will measure your body weight using a digital scale (lightly clothed with t-shirt and shorts, or similar). We will also measure your height.	Day 1
Body Composition and Fat Percentage	We measure your body composition (percent lean body weight and percent body fat) using a machine called DEXA (dual-energy x-ray absorptiometry). You will lie still on your back, on a padded table for about 10 minutes, while an X-ray scanner moves across your body. If you opt out of the DEXA measurement, we will measure your percent body fat by pinching 7 different areas on your skin instead.	Day 1
Hand/Finger Characteristics	We will measure the volume of your hand and index finger by having you place your hand and index finger in a container of water. We will measure the length, depth, width, and circumference of your index finger using a string and ruler. We will measure the length and width of your hand using a ruler. We will also image your hands using a 3D scanner.	Day 1
Skin Pigmentation	We will measure the pigmentation of the skin on your hand and upper arm using a device that shines a light on your skin. The device is gently placed on the skin surface for about 1-3 seconds.	Day 1
Background Surveys	You will fill out brief surveys that include questions about your race and ethnicity, previous exposure to cold environments, general stress level in your everyday life, and self-assessed socioeconomic status.	Day 1
Blood Pressure and Heart Rate	Your heart rate and blood pressure will be measured before and about every 10 minutes throughout testing.	Days 3, 4, 6, and 7
Body Temperature	Your internal body temperature will be measured using a temperature pill that you will swallow or place as a suppository (self-insert into rectum). We will instruct you on how to place or swallow the pill. The pill sends a signal to a monitoring device which displays the pill temperature. If a pill stops transmitting during a trial, you may be asked to swallow or insert a second pill as a suppository to ensure temperature measurement.	Days 3, 4, 6 and 7

	You will wear a bracelet indicating that you should not have an MRI while the pill is inside of you until elimination from the body is confirmed by study staff.	
Skin Temperature (sensor)	Your skin temperature will be measured continuously by sensors taped to your skin in up to 12 places on the body (back, forearm, tricep, calf, thigh, top of foot, chest, top of hand, top of two fingers, and top of toe). If you have a lot of body hair, these sites may need to be shaved so that the sensors have good contact with your skin.	Days 3, 4, 6, and 7
Skin Temperature (Imaging)	The temperature of your hands and feet (including your fingers and toes) will also be measured three times using a camera that measures the amount of heat in your skin.	Days 4 and 7
Body Heat Production	We will collect the air you breathe out before and about every 20 minutes during cold exposure for about a 3-5 minute period. You will wear a nose clip and breathe into a mouthpiece (similar to that used for snorkeling), which will be attached to a computer. The computer calculates how much energy you are burning.	Days 4 and 7
Thermal Comfort and Pain Level	We will ask you to tell us how warm or cold you feel (your thermal comfort) and if/how much pain you feel (on your whole body, hand, and foot), before and about every 10-15 minutes during cold exposure.	Days 3, 4, 6, and 7
Skin Blood Flow	A weak laser light will be placed on your skin to measure the amount of blood moving through the small blood vessels in your skin. The measurement is painless and causes no damage to the skin or muscle. Your finger, hand, and forearm skin blood flow will be measured continuously throughout the testing sessions.	Days 3, 4, 6, and 7
Hand Dexterity and Strength	As described above, dexterity tests consist of placing pegs into holes; assembling pegs, washers, and sleeves; loading dummy cartridges into a magazine; and moving disks on a board. Finger and hand strength tests consist of pinching different fingers together on a pinch device and by squeezing a device with your whole hand. Your dexterity and strength will be measured about 10 times during the familiarization visits (Days 1, 2, and 5). On Days 4 and 7, your dexterity and strength will be measured before entering the cold air room and after 65 minutes of cold air exposure.	Days 1, 2, 4, 5 and 7
Blood Draws	We will draw your blood before and after you consume the pill. We will take blood samples by putting a needle into a vein of your arm; this is called venipuncture. This is the standard method used to obtain blood for tests. There are 12	Days 3, 4, 6, and 7

	blood draws in the study; approximately 3.2 teaspoons will be removed each time, total about 4/5 cup. You will feel slight pain and discomfort when the needle goes into the vein. A bruise may form at the site, but this will gradually disappear. Sometimes the technicians will miss a vein or not get enough blood for the test. They may ask you to repeat venipuncture on a different vein in your arm. You have the right to refuse repeat attempts. Samples of your blood will be sent to Walter Reed Army Institute of Research to measure the level of MitoQ in the blood. No genetic tests will be performed in this study on your blood.	

HOW LONG WILL I BE IN THE STUDY?

You will be in this study for about 4-6 weeks, total for about 20 hours. If you are a male participant, the total time is approximately 4-5 weeks, which includes a 2-week time period between taking the MitoQ and placebo treatments, so that any extra MitoQ can leave your body.

If you are a female participant, the total time will be approximately 5-6 weeks, because we need to test you in the same part of your menstrual cycle for both treatments. For example, we can test Treatment 1 in the first part of your menstrual cycle (within approximately 7 days after the start of their period) and then test Treatment 2 in the first part of your next menstrual cycle. Alternatively, we can test Treatment 1 in the second half of your menstrual cycle and then test Treatment 2 in the second half of your next menstrual cycle.

For oral contraceptive users, we will complete testing for both Treatments 1 and 2 in placebo phases of the contraceptive or complete testing for both treatments in active hormone phases of the contraceptive. The testing schedule for non-hormonal and hormonal IUD users will be the same as for eumenorrheic females. If a female participant reports not having a cycle, Treatment 2 will take place a minimum of 3 weeks after Treatment 1.

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 **should not** participate in this study if any of the following applies to you:

- Have had a prior cold injury (e.g., frostbite, trench foot, chilblains) that has lasting effects on your responses to cold or continuing symptoms
- Have Raynaud's Syndrome
- Have cold-induced asthma/bronchospasm
- Have previous hand/finger injuries that impair dexterity and hand function
- Have metal hardware (plates, screws) in the forearms and hands
- Smoke, vape, or use smokeless tobacco or other nicotine-containing products (unless have quit more than 4 months prior)
- Take certain medicine or supplements regularly
- Have known allergies to medical adhesives
- Have a known allergy to MitoQ
- Difficulty swallowing pills
- Not willing to have small areas of skin on the body shaved (if it is necessary for study instrumentation to have good contact with your skin)

- Have a planned MRI during the study or within 3 days after completing a cold test
- Have a heart, lung, kidney, muscle, or nerve disorder(s)
- Are pregnant, planning to become pregnant, or breastfeeding
- Have a history of disease of the gastrointestinal tract including (but not limited to) diverticulosis, diverticulitis and inflammatory bowel disease, peptic ulcer disease, Crohn's disease, ulcerative colitis; or previous gastrointestinal surgery
- Have a history of renal disease including (but not limited to) chronic kidney disease, acute kidney injury, kidney stone disease, glomerular disease, or nephritis
- Have donated blood within 8 weeks of the study or plan to donate blood during the study
- Have lesions on a significant portion of the upper extremities due to skin pigmentation disorders (e.g. vitiligo, psoriasis)

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

- Consume the **same** types and quantities of food the day before each testing visits.
- **Not** exercise and not consume caffeinated or alcoholic beverages 12 hours before each testing visit
- **Not** consume food 10 hours before each testing visit
- **Not** have a magnetic resonance imaging (MRI) test while the core temperature pill is in your body.
- **Not** consume antioxidant-rich foods 48 hours before each testing visit. Antioxidant-rich foods that you will be asked to avoid include the following:
    - Beans
    - Berries, pomegranates, apples, red grapes, and plums
    - Spinach, kale, and cabbage
    - Dried fruits
    - Pecans, walnuts, pistachios, chestnuts, and sunflower seeds
    - Broccoli, cauliflower, carrots, artichokes, asparagus, and beets
    - Dark chocolate
    - Cinnamon, cloves, allspice, oregano, mint leaves

HOW MANY PEOPLE WILL BE IN THE STUDY?

We are recruiting up to 60 volunteers with the goal of collecting complete data on 30 volunteers (one subset of 15 Black subjects and one of 15 non-Black subjects). All screening and enrollment will stop once complete data has been collected from 30 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?

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

Source of Risk	Risk	How We Minimize Risks
Cold Exposure (Hand and Body)	• Cold-induced asthma/bronchospasm	• Symptoms and blood pressure are monitored during cold exposure

	• Cold intolerance (pain, numbness, stiffness, change in blood pressure)	• Symptoms are only temporary and disappear after cold exposure
Core Temperature Pill	• Damage to rectal membrane or retention in gastrointestinal tract • Not compatible with MRI	• Instructions and lube provided for self-insertion • Bracelet provided to prevent inadvertently having a MRI while the pill is inside the body • Excluded if you have difficulty swallowing large pills or a history of disease/surgery of the gastrointestinal tract
Adhesives	• Skin irritation • Allergic reaction	• Excluded if you have an allergy to adhesive • Skin is properly cleaned and monitored
DEXA	• Low dose radiation • Risk to fetus	• 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
Laser-Doppler (Skin Blood Flow)	• Retinal damage	• FDA-approved laser • Instructed to never stare into the laser
3D Hand Scanner	• Retinal damage • Visual disorientation and associated lightheadedness • Facial twitching • Seizure due to strobing laser	• Instructed to never stare into the laser at any time • Scan will immediately stop if any associated risks are observed or reported
Blood Draw	• Pain, skin irritation • Dizziness, fainting • Bruising • Infection	• Performed by credentialed staff members • Proper and sterile techniques used
Blood Pressure and Heart Rate Monitoring	• Skin irritation or chaffing from blood pressure cuff or heart rate strap	• Skin is monitored for skin irritation
Dexterity and Strength Tests	• Mild anxiety related to completion of timed tasks	• You practice dexterity and strength tests until you are proficient and feel comfortable with them before testing

MitoQ Ingestion	• Nausea/GI distress • Vomiting • Diarrhea • Insomnia • Allergy	• Excluded if you have an allergy to MitoQ • Supplement is given approximately 30 min before breakfast

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 a countermeasure that protects Soldiers from cold injury and helps them maintain their hand function during cold-weather operations.

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?

If you would like a copy of your DEXA (body composition) results, or a copy of the final report when the study is complete, please contact Dr. Billie Alba at 508-206-2171 or billie.k.alba.civ@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?

You can earn $50 per blood draw (12 in this study), for a total of up to $600 for completing the study. The blood draws for which you will be compensated does not include the blood draw taken during your medical clearance. If you are a Soldier, you may be eligible for hazardous duty pay for testing in the cold. Although paperwork will be submitted for all Military personnel if you perform any testing in the cold, it is not guaranteed that you will receive it.

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 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. Billie Alba at Office Phone: 508-206-2171; Cell Phone: 352-316-5023; or e-mail: billie.k.alba.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?

To protect your privacy, any of your research-related records or data will be labeled or “coded” with an assigned research participant number that will not include your name or social security number. The PI (or designee) will keep the link between your participant number and your research records on a password protected computer. The PI (or designee) is the only person who will be able to match your research participant number with any of your personal identifying information. The link between your name and participant number will be destroyed when the protocol is closed. All the study data that we get from you will be kept locked up or in password-protected computer files. Only coded blood samples will be sent to collaborators at Walter Reed Army Institute of Research.

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 you sign the photo release form, we may use your picture in presentations, but we will not link any of your data directly with a picture. These pictures are used to help describe the testing conditions. If you do not sign the photo release form, no photos of you will be taken. If any photographs or video recordings are taken of you inadvertently, they will be destroyed immediately. You do not have to sign a photo release to participate in this study.

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

- 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 (ORQC)
- US Army Research Institute of Environmental Medicine, Office of Medical Support and Oversight (OMSO)
- Food and Drug Administration (FDA)

Once information that personally identifies you is removed from your data, your data 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 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 or future relationships with USARIEM.

If you decide to withdraw, you may do so by notifying the PI or research staff verbally or in writing. We may still use the data and blood samples we have collected. You will be paid $50 for every successful blood draw that you complete.

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. Billie Alba. Office phone: 508-206-2171; Cell Phone: 352-316-5023; e-mail: billie.k.alba.civ@health.mil.

If you believe you may have a research related injury or illness, please immediately contact Dr. Alba at 352-316-5023 (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 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.

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