U.S. Army Research Institute of Environmental Medicine

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: The effects of cold habituation on peripheral blood flow, hand function, and thermal comfort

Principal Investigator: Billie K. Alba, PhD

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 solutions that allow Soldiers to function and use their hands better in a cold environment. 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 this research is to develop a new way for Soldiers to keep their hands warm and functional in a cold weather environment. The main purpose of this study is to see if 8 days of exposure to cold temperatures improves blood flow to the hands, thermal comfort, and hand function in the cold.
Duration	You will be in this study for about 4-5 weeks.

Procedures	While you are in the study, you will • Participate in **9 days of cold air exposure** (46°F; 2 hours per day) • Complete **3** skin blood flow testing sessions, which include procedures that cool small areas of skin on your arm and your whole-body. • Complete a total of **6** blood draws • Self-insert a temperature pill into the rectum on **5** days • Perform laboratory testing of hand function and dexterity
Precautions	You will be asked to: • **Not** exercise or consume caffeine or alcohol **12** hours prior to testing (12 study days total) • **Not** smoke or use tobacco products **8** hours prior to testing (12 study days total)
Drugs/Devices	No drugs will be used in this study. Devices used in this study include the E-Celsius® Performance Capsule (BodyCap, Saint-Clair, France), and Local Cooling System (TE Technology Inc., Traverse City, MI). *The E-Celsius® Performance Capsule will be used to measure internal body temperature and the Local Cooling System will be used to maintain or decrease local skin temperature. The devices are not FDA-approved.*
Risks	The **main** risks from being in this study are: • Lightheadedness or fainting in response to needles • Skin sensitivity to adhesives • Intolerance or discomfort during exposure to cold temperatures
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 helps Soldiers maintain manual dexterity and better able to complete tasks during cold-weather operations.
Payment	You will be paid for your participation in this study.

Covid-19 Risk Mitigation	If you agree to participate, you will be asked to follow all COVID-19 risk mitigation procedures in place at USARIEM during the time of data collection. You may be asked to wear facemasks and use hand sanitizer or wash your hands during data collection activities (in accord with prevailing recommendations at the time of data collection) and may be asked to wear gloves (i.e., nitrile gloves) during data collection.

WHY IS THIS RESEARCH BEING DONE?

U.S. military personnel operating in cold weather often experience a loss of hand function and joint mobility due to a decrease in skin temperatures and blood flow. Reduced hand function has severe adverse impacts on the ability to perform important military tasks such as digital command and control functions, weapons use, and delivery of medical treatment. Thus, methods to maintain hand and finger mobility in cold weather environments are needed.

The purpose of this research is to develop a new way for Soldiers to keep their hands warm and functional in a cold weather environment. Humans can adapt and become more tolerant to cold environments if they are frequently exposed to cold temperatures. However, we do not know if repeated cold exposure can improve blood flow and maintain hand dexterity in the cold. The main purpose of this study is to see if 8 days of exposure to cold temperatures improves blood flow to the hands, thermal comfort, and hand function in the cold. Another purpose is to see how the function of blood vessels in the skin changes in order to increase blood flow to the hands in the cold.

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

You may take part in this research if all of the following applies to you:

- Are 18-39 years old
- In good health as determined by OMSO General Medical Clearance

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

- Have a history of cold injuries of any severity (e.g., frostbite, trench foot, chilblains)
- 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
- Take certain medicine or supplements regularly
- Have known allergies to medical adhesives

- 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 or within 2 days after completing a cold test
- Have difficulty swallowing large pills
- 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 heart, lung, kidney, muscle, or nerve disorder(s)
- Are pregnant or breastfeeding

If you are eligible to participate in the study, you will undergo 2-hour cold air exposures at 46°F on 9 days (8 of them will be on consecutive days). During the cold exposures, you will wear shorts and a sports bra (for women). While exposed to the cold, you will not be allowed to engage in any behavioral thermoregulation, including excessive movement, "huddling", or closing the hands. You will allowed to use the bathroom only if it is absolutely necessary, but no breaks can otherwise be permitted. In some circumstances, you may be asked to urinate in a sterile jug or portable urinal in the cold room. In the event that 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 2 hours of cold air exposure.

Before, during, and after the 8 consecutive days of cold exposure, you will participate in a set of experiments, which will include 1) tests that measure skin blood flow and 2) tests that measure hand dexterity and strength. The timeline of the study is outlined in the following table and 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	Familiarization	1 hour
4	Skin Blood Flow Testing (Baseline)	3 hours
5	Cold Air Exposure + Dexterity Test (Baseline)	3.5 hours
13	Skin Blood Flow Testing (Pre)	3 hours
14	Cold Air Exposure + Dexterity Test (Pre)	3.5 hours
15-20	Cold Air Exposure	3 hours/day
21	Cold Air Exposure + Dexterity Test (Post)	3.5 hours
22	Skin Blood Flow Testing (Post)	3 hours

Study Visits

1. Orientation:

   Weight, height, body fat, pregnancy, and cold exposure evaluation: We will measure your height and weight and will record your age.

   We will also measure your percent body fat using a machine called DEXA (dual-energy x-ray absorptiometry). For women, we will test to make sure that you are not pregnant by having you complete a urine pregnancy test on the day of the DEXA, your result will be confirmed and recorded by a member of the research team. If you are pregnant, you cannot have the scan or participate further in the study. You may decide to not have your body fat percentage measured by DEXA. We will also measure your percent body fat by pinching 10 different areas on your skin.

   We will measure the volume, surface area, length and width of your hand. We will also measure the volume, length, depth, width, and circumference of your index finger.

   We will also ask you to complete a brief survey asking you questions about your previous exposure to cold environments.

2. Familiarization Visits

   You will practice the dexterity and strength tests about 10 times (over about 3 sessions; refer to Table 1 above). Dexterity tests consist of placing pegs into holes; assembling pegs, washers, and sleeves; 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.

   We will also have you sit in a thermal chamber (set at 46°F) for approximately 5-10 minutes during the first familiarization session so that you know what it will be like on an experimental day.

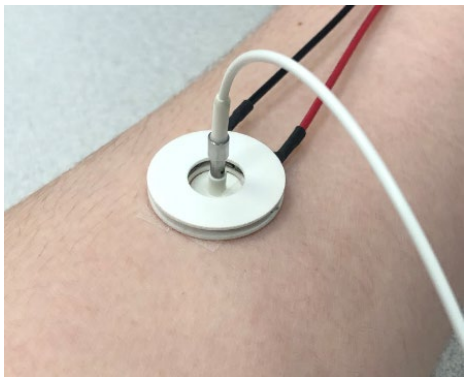
3. Skin Blood Flow Testing:

   Skin blood flow testing will be performed on Study Days 4, 13, and 22 (a week before, immediately before and immediately after 8 days of cold exposure; see Table 1 above).

   Whole-body cooling and rewarming: You will wear a whole-body suit that has tubing lining the inside through which we will circulate cold water to cool your whole body. Men will wear shorts under the suit. Women will wear shorts and a sports bra.

   Lukewarm water (~93.2°F) will run through the suit. After about 80 min, cool water will run through the body suit for about 30 minutes (until your body skin temperature reaches about 87°F). We will keep your skin temperature at around 87°F for about 10 minutes. The skin over your entire body will feel cold. After your skin is cooled, lukewarm water will run through the suit to return your skin temperature to normal.

   Local skin cooling and rewarming*:* We will also cool three small areas of your skin by taping three small cooling units (see picture below) on your arm. If you have a lot of body hair, these sites may need to be shaved so that the cooling units have good contact with your skin.



A picture of the cooling unit placed on the forearm.

The temperature of the three cooling units on your arm will be changed as follows:

Cooling Unit #1: Unit 1 will be set at a lukewarm (about 93°F) temperature for about 20 minutes. We will decrease the temperature of the cooling unit to around 75°F for about 40 minutes. Your skin will feel cold at a small area on your arm. We will then bring the temperature of the cooling unit back up to about 93°F until the end of the experiment (about 80 minutes).

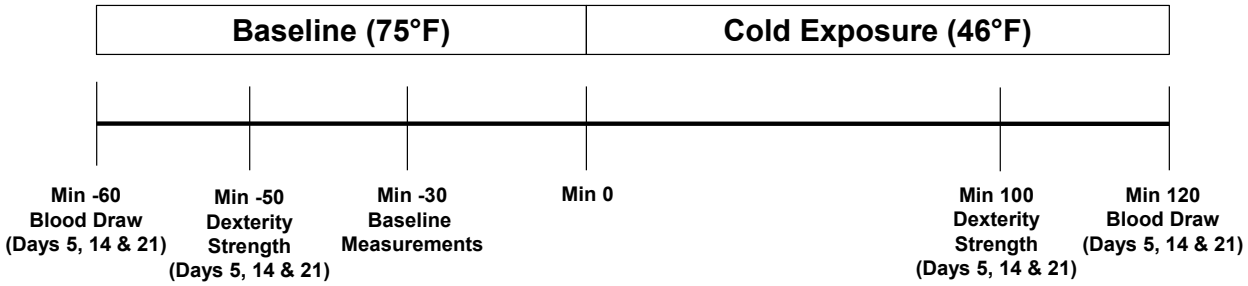
Cooling Unit #2: Unit 2 will be set at a lukewarm (about 93°F) temperature and will stay at a lukewarm temperature for the entire experiment.

Cooling Unit #3: Unit 3 will be set at a lukewarm (about 93°F) temperature for about 80 minutes. We will decrease the temperature of the cooling unit to about 75°F for about 40 minutes. Your skin will feel cold at a small area on your arm. We will then bring the temperature of the cooling unit back up to about 93°F for about 20 minutes.

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

4. Cold Air Exposures and Dexterity Tests

On Study Day 5, and Study Days 14 through 21 (8 days in a row), you will sit in a 46°F room for 120 minutes. You will be wearing shorts and a sports bra (for women). You will not be allowed to huddle, close or rub your hands together, or do any physical activity while in the cold room. We will be taking measurements of blood pressure, heart rate, body temperature, skin temperature, body heat production, thermal comfort and pain level, and skin blood flow (described further in Table 2 below). On Study Days 5, 14, and 21, we will also measure dexterity and strength and draw your blood as shown in the following figure. On Study Days 5, 14, 17, 19, and 21, you will be asked to arrive at the laboratory following an overnight (10 hour) fast. We will give you a standard breakfast when you arrive.



We will collect measurements in room air (about 75°F) prior to entering the cold chamber and then again at various times during the cold air exposures, as described in Table 2 below.

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 (women 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.	Day 1
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, Fat Percentage, and Hand/Finger Characteristics	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. You may opt out of the DEXA measurement. We will measure your percent body fat by pinching 10 different areas on your skin. 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 hand using a 3D scanner.	Day 1
Cold exposure Background	You will fill out a brief survey that includes questions about your previous exposure to cold environments.	Day 1
Blood Pressure and Heart Rate	Your heart rate and blood pressure will be measured before and every 5-10 minutes throughout cold exposure.	Days 4-22

Body Temperature	Your internal body temperature will be measured every 10 min using a temperature pill that you will place as a suppository (self-insert into rectum). We will instruct you on how to place the pill. The pill sends a signal to a monitoring device which displays the pill temperature. In the event that a pill stops transmitting during a trial, you may be asked to insert a second pill to ensure continuous temperature measurement.	Days 5, 14, 17, 19, and 21
Skin Temperature (sensor)	Your skin temperature will be measured by sensors taped to your skin in up to 10 places on the body (back, forearm, tricep, calf, thigh, top of foot, chest, top of hand, top of finger, 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 4, 5, 13, 14, 17, 19, 21, and 22
Skin Temperature (Imaging)	The temperature of your hands and feet (including your fingers and toes) will also be measured using a camera that measures the amount of heat in your skin.	Days 5, 14, 21
Body Heat Production	We will collect the air you breathe out before and every 20 minutes during cold exposure for 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 5, 14, 17, 19, and 21
Thermal Comfort and Pain Level	We will ask you to tell us how warm/cold you feel (your thermal comfort) and if/how much pain you feel before and every 20 minutes during cold exposure.	Days 5, 14, 17, 19, and 21
Skin Blood Flow	A weak laser light will be held over 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 hand, finger, and/or forearm skin blood flow will be measured continuously throughout the testing session.	Days 4, 5, 13, 14, 17, 19, 21, and 22
Hand Dexterity and Strength	As described above, dexterity tests consist of placing pegs into holes; assembling pegs, washers, and sleeves; 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 before entering the cold air room and after 100 minutes of cold air exposure.	Days 1, 2, 3, 5, 14, and 21
Blood Draws	We will draw your blood before and after the cold exposure. 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 6 blood draws in the study; approximately 2 teaspoons will be removed each time, total about 12 teaspoons. You will feel	Days 5, 14, and 21

	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. 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 4-5 weeks, total for about 41 hours.

WHAT PRECAUTIONS DO I NEED TO TAKE?

- Not exercise and not consume caffeinated or alcoholic beverages 12 hours before each testing session
- Not smoke or use tobacco products 8 hours before each testing session

HOW MANY PEOPLE WILL BE IN THE STUDY?

We are recruiting up to 35 people so we can collect complete data on 15 people.

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 Air Exposure	• Cold-induced asthma/bronchospasm • Cold intolerance (pain, numbness, stiffness, change in blood pressure)	• Symptoms and blood pressure are monitored during cold exposure • Symptoms are only temporary and disappear after cold exposure
Local Skin Cooling	• Sudden change in temperature due to electrical current leak, causing local skin damage or burn • Skin discoloration	• Electrical safety checks are performed on equipment • Temperature of cooling units will be changed gradually by researchers • Skin discoloration and local changes in temperature are only temporary
Whole-body Skin Cooling	• Cold intolerance • Stiffness • Change in blood pressure	• Symptoms and blood pressure are monitored during cold exposure • Symptoms are only temporary and disappear after cold exposure • Cooling will be reduced or stopped if you feel too cold or begin to shiver
Core Temperature Pill	• Damage to rectal membrane • 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
Test Equipment	• Electric shock	• All electronic test equipment is operated by trained personnel • Equipment is inspected for electrical safety prior to use
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
Laser-Doppler (Skin Blood Flow)	• Retinal damage	• FDA-approved laser • Instructed to never stare into the laser
Blood Draw	• Pain, skin irritation • Dizziness, fainting • Bruising • Infection	• Performed by credentialed staff members • Proper and sterile techniques used
Blood Pressure Monitoring	• Skin irritation or chaffing from blood pressure cuff	• 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
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

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 helps Soldiers maintain manual dexterity and better able to complete tasks during cold-weather operations.

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.

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?

If you are a soldier or DoD civilian, you can earn $50 per blood draw (6 in this study), for a total of up to $300 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 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.

If you are a non-DoD civilian, you can earn up to $480 for completing the study. Payment will be processed within two weeks of study completion/end and you will receive payment within approximately ten weeks of study completion/end. Payment will be made by direct transfer to your bank account.

Your social security number will be needed to process 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. Dr. Alba (or designee selected by the PI) will keep the link between your participant number and your research records on a password protected computer. Dr. Alba (or designee selected by the PI) 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 Dr. Alba closes the protocol. All the study data that we get from you will be kept locked up or in password-protected computer files. Financial information, such as social security number and bank account number that is required for direct deposit of compensation for research, will be kept in a separate locked file cabinet from the research records. Only the principal investigator (or designee) will have access to this cabinet. These records will be destroyed upon project completion and compensation is complete. No biospecimens will be retained beyond the completion of this research effort.

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.

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

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 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. If you are a soldier or DoD civilian, you will be paid $50 for every successful blood draw that you complete. If you are a non-DoD civilian, you will be paid $20 for every hour of cold exposure and $40 per skin blood flow experiment 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