Modafinil to Optimize the Performance of Cold-Stressed Sleep-Deprived Personnel

Protocol: 23-19HC, NCT Number: NCT07830056

Informed Consent Form *(version: 4/22/2026)*

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

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: Modafinil to Optimize the Performance of Cold-Stressed Sleep-Deprived Personnel

Principal Investigator: Dr. Harris R. Lieberman, PhD

Introduction: You are being asked to participate in a research study because you are a healthy man or woman between 18-39 years old (17-year-old Active-Duty service members may participate). 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 decision. You can also choose to stop participating at any time during the study.
Purpose	This study will help us determine if a medication, modafinil, which is a wake-promoting and body-temperature-elevating medicine, will enable better performance and mood in cold environments. By “performance” we mean both cognitive and physical performance. By “mood” we mean self-ratings of feelings like fatigue, confusion, vigor, aggressiveness, etc.
Duration	You will be in this study for 12 days total, over the course of approximately 2 weeks, but may be longer based on your schedule.

Procedures	While you are in the study you will participate in 2 test cycles separated by a two-day washout/recovery (no testing) period: • You will be provided a standardized diet to consume 48 hours before testing. You will also be provided with food during each testing cycle. • You will be outfitted in physiological monitoring devices and cold weather clothing during testing cycles. • During each testing cycle, you will remain awake for 26 hours and sit/perform in a cold chamber for 12 of the 26 hours. You will be in the cold chamber set to 14°F for 3 hours at a time, with 1-hour breaks outside the chamber at 50-68°F. • During each testing cycle, you will receive 2 oral doses of the active drug modafinil or 2 oral doses of an inactive placebo. You will not be told which (drug or placebo) you are being given in which testing cycle but you will receive the drug in one cycle and the placebo in the other. • There will be two "washout" or "recovery" days in between two testing cycles where you will not be in the lab. Throughout each testing cycle you will be tested on several cognitive tests, two physical tests, and two self-report mood tests a total of four times.
Study Restrictions and Requirements	• You must be 18-39 years old to participate. Active duty service members may be 17 years old. • You must not have donated blood within 8 weeks prior to study start • You must not be currently using, or have used in the last three months, modafinil or armodafinil. • You must not be allergic to modafinil or armodafinil. • You will be required to refrain from vigorous exercise, caffeine, nicotine, and alcohol for 24 hours prior to and during each testing day. • Females must not be pregnant, trying to become pregnant, or using contraceptives (except condoms). • You must refrain from taking dietary supplements (except a multivitamin) within one week of initial screen and at any time while enrolled in the study. • You must be willing to consume only the provided study diet during the study. • You must not have or obtain an injury that limits your physical performance or ability to exercise. • You can not be regularly or intermittently be taking any over the counter or prescription medication that our medical staff determines will interact with your safety or results of the study. • You must have no known blood abnormalities including low hemoglobin or hematocrit

Drugs/Devices	The drug used in this study is: modafinil • *Modafinil is an FDA approved drug. The use of modafinil to alleviate cold stress in Army personnel is considered "Off Label."*
Risks	The **main, potential** risks from being in this study are: • Possible skin irritation from the cold exposure. Overexposure to cold may lead to freezing injuries of the skin and generalized hypothermia. In some cases, cold exposure can produce asthma like symptoms. • Likely fatigue from the multiple test sessions and long hours of wakefulness. Total sleep-deprivation potentially increases the risk of cold weather injuries. • Possible headache, nausea, nervousness, stuffy nose, diarrhea, back pain, anxiety, trouble sleeping, dizziness, and upset stomach are the most common side effects from the modafinil. Serious side effects such as chest pain, mental problems, and rash can also occur. • Local muscle discomfort and fatigue during and shortly after physical exercise, with possible muscle soreness afterwards. • Magnetic resonance imaging can cause overheating of the temperature pill. • Body composition test will use a small amount of radiation that can cause harm to an unborn fetus. Steps to handle these risks are described later in this consent form.
Benefits	There are no direct health or other benefits related to participating in this study. Information gathered from this research may benefit other people in the future.
Alternatives	The only alternative is to not participate.
Payment	Civilian volunteers who are not government employees will be paid for participation in this study (up to $1,440). Active-duty military personnel may be eligible for hazardous duty pay (but this is not guaranteed, and the study investigators do not make the determination that you will receive it).

WHY IS THIS RESEARCH BEING DONE?

Military training and operations involve a unique combination of psychological, physical, and environmental stressors. Cold-weather operations is one such stressor. Sleep deprivation is another. Enhanced cold-weather/sleep-deprived performance is an essential force multiplier in certain operations including those under Arctic conditions. The strategic importance of operating in these cold environments is recognized by our Nation's leaders.

Modafinil is a controlled substance that is readily-available, operationally-feasible countermeasure to mitigate fatigue and potentially address cold stress that is currently available in the military formulary and is a generic drug approved by the FDA to increase wakefulness in adults with narcolepsy, sleep apnea and shift work sleep disorder.

This study will verify the utility of modafinil as a cold-stress/sleep-deprivation countermeasure that will optimize warfighter performance in cold and fatiguing environments.

WHAT WILL HAPPEN DURING THIS RESEARCH?

If you agree to participate in this research, you will be a study volunteer for about 12 days over a 2-week period. You will be asked to do the activities in the table below. This is an example schedule and the order you complete each task may vary.

Study Phase	Duration/Activities
Pre-Testing, Baseline, and/or Training Procedures	2 short days prior to the testing cycles
	• Medical Screening (*once for entire study, 1 hour*) • Height measurement (*1 time, 1 min*) • Body weight measurement (*fasted, 1 min/measurement*) • Urine pregnancy test 24 hours before study intervention and DEXA (females) • Body Composition: DEXA Scan (*fasted, approximately 10 min*) • Wrist-worn sleep/activity monitor • Resilience • 2-3 practice sessions on physical performance tests • 2-3 practice sessions on computerized cognitive and mood tests
In-laboratory Testing in Cold and Sleep-Deprived Conditions both With and Without Modafinil	2 two-day-long testing cycles (a total of 4 days)
	• Alertness • Working memory • Verbal reasoning • Risk taking behavior • Mood • Aggression • Exertion • Pain • Feelings • Arousal • Response inhibition • Cognitive flexibility • Exercise tolerance • Muscular strength • Manual dexterity • Core body temperature • Skin temperature •
Washout Period	2 two-day washout periods (after test cycles)
	• Wrist-worn sleep/activity monitor throughout • No other study activities

Sample Schedule

Note: Testing times are approximate and may vary. Previous week schedule TBD based on your schedule.

Time	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9
	Baseline (start study diet)	**Study Diet**	**MODAFINIL Sleep Deprivation Run- in (Rested) Cold**	**MODAFINIL Sleep Deprivation Testing (Sleep Deprived) Cold**	**Washout/ Recovery**	**Washout/ Recovery**	**PLACEBO Sleep Deprivation Run- in (Rested) Cold**	**PLACEBO Sleep Deprivation Testing (Sleep Deprived) Cold**	**Washout/ Recovery**	**Washout/ Recovery**
0:00				Break				Break		
1:00				Cold Testing				Cold Testing		
2:00				Cold Testing				Cold Testing		
3:00				Cold Testing				Cold Testing		
4:00				Break				Break		
5:00				Cold Testing				Cold Testing		
6:00			Breakfast, DOSE	Cold Testing			Breakfast, DOSE	Cold Testing		
7:00			Cold Testing	Cold Testing			Cold Testing	Cold Testing		
8:00	Breakfast	Breakfast	Cold Testing	Breakfast, Release	Breakfast	Breakfast	Cold Testing	Breakfast, Release		
9:00	Training		Cold Testing				Cold Testing			Return Activity Monitor
10:00	Training		Monitoring				Monitoring			
11:00	Training		Monitoring				Monitoring			
12:00	Lunch, Release	Lunch	Lunch	Lunch	Lunch	Lunch	Lunch	Lunch		
13:00	Training		Monitoring				Monitoring			
14:00	Training		Monitoring				Monitoring			
15:00	Training		Monitoring				Monitoring			
16:00	Return		Monitoring				Monitoring			
17:00			Monitoring				Monitoring			
18:00			Monitoring				Monitoring			
19:00			Study prep				Study prep			
20:00	Dinner	Dinner	Dinner, DOSE	Dinner	Dinner	Dinner	Dinner, DOSE	Dinner		
21:00	Release		Cold Testing				Cold Testing			
22:00			Cold Testing				Cold Testing			
23:00			Cold Testing				Cold Testing			

Screening Procedures:

After signing the consent form, you will be asked to answer questions about your medical history and make an appointment for a medical screening visit.

Demographic and Background Form: You will be asked to complete a form about your medical history, exercise, resilience, and, previous cold exposure. Individuals identifying certain medical conditions (e.g., cold sensitivity and Raynaud's disease) during the survey will be excluded from the study.

Medical Screening: You will meet with the staff of the USARIEM Office of Medical Support and Oversight (OMSO) to undergo a medical clearance. The one-hour medical screening visit will be done at USARIEM or at your respective unit's medical oversight location. You will be told about any possible medical concerns found by the screening by the medical staff. Health problems found during the screening process will be documented by the medical staff, and you will be provided a copy. You are encouraged to make an appointment with your doctor to follow up with a full evaluation of the identified health concerns. If you have any evidence of existing physical, mental and/or medical conditions that would increase your risk of participating, you will be excluded.

Study Procedures:

Body Composition: We will use dual energy x-ray absorptiometry (DEXA) scan to measure your total body, muscle, and fat mass once during the study. For this, you will lie on your back and remain still for about 8-10 min while the x-ray scanner moves over your body. The DEXA will not cause pain or discomfort and you will be provided with these results if you request them.

Height & Weight: A researcher will measure your height and weight at baseline. All weight measurements will be taken while wearing a t-shirt and shorts. This will take approximately 5 min.

Familiarization: Prior to testing, there will be two familiarization days providing you with the opportunity to practice taking the cognitive, mood, and physical performance assessments. You will also practice swallowing a (placebo) pill of the same size and shape as the modafinil and placebo pills you will be provided during the study. You'll also be able to experience a brief cold exposure (~15min) in the cold chamber while wearing the same cold weather gear you will be wearing during testing.

Modafinil/placebo Medication by Mouth: During each of the 2-day testing cycles, you will take two pills 14 hours or so apart. Each pill contains 200 mg of modafinil or a placebo (sugar-like pill). Thus, you will get a total of 400 mg of modafinil during one cycle and 400 mg of placebo during another cycle. Neither the study staff nor you will know which intervention you'll receive in which cycle, but you will receive both interventions should you complete the study. After the study is complete, we will be able to unblind ourselves and you should you want to know. Research personnel will administer the pills and observe you when you take the pills to ensure compliance. Research personnel will conduct medical oversight throughout your participation in the study.

Study Diet: 48 hours before and during testing cycles, you will be provided with a standard study diet. Study diets will be made from military combat rations (Meal, Read-to-Eat) and commercially available food items. The amount of food provided to you will be based on your body weight at the start of the study. You will be asked to return wrappers and containers from the study diets.

Cold Exposure/Sleep-Deprivation: On the testing days (two 2-day testing cycles), you will remain in a cold chamber for a total of 12 hours during the 26-hour testing cycle. The temperature of the chamber will be 14˚F (3 hours). You will have 1 hour of relief from the cold chamber (50-68˚F) between consecutive cold-chamber exposures throughout the testing cycle. You will be allowed to leave the cold chamber briefly when you need to use the bathroom but encouraged to use the restroom during designated break times. You will wear the Generation 3 Extended Cold Weather Clothing System or equivalent during cold exposures, which contains multiple layers of protection (i.e, silkweight and midweight underwear, soft shell coat, fleece hat, trigger mittens, heavy wool socks, cold-wet boot). Trigger mittens will be replaced with contact gloves during the cognitive and dexterity tests. The clothing worn during the testing cycles will be provided by the research team. You will return this clothing at the end of each testing cycle.

During this time, you will be asked to complete several test sessions, each of which contains a series of cognitive, mood, and physical tests. Within each session the testing will last approximately three hours and then you will have approximately 1-hour break at the end (thus, each session will be 4-hours in length). You will not be allowed to sleep during either of the two testing cycles. Your core body temperature will be measured continuously with a temperature monitoring capsule. You will insert the temperature monitoring capsule via rectal suppository the morning of testing. If you prefer to swallow the pill instead, you may do so initially. The study team will instruct you on how to best swallow the capsule and provide it to you for ingestion the night prior to data collection. However, if you pass the pill in the morning of or during data collection (and the temperature data confirms that) or a pill stops transmitting data- we will need you to insert an additional capsule rectally to continue. This is both for your safety and the accuracy of the data. Sensors will also be adhered to your chest, triceps, hand, thigh, calf and foot with medical tape to provide information on the temperature of your skin. During the 1-hour break periods you will have access to various types of entertainment such as streaming video, computer games, etc. Times are approximate and may vary. You will be provided counseling after cold exposures and sleep-deprivation as part of the debriefing process. We will remind you that you may experience a period of sleepiness and should not operate cars or machinery for 12-16 hours after your participation. To ensure your safety, a member of the research team will escort you to the barracks.

Cognitive and Mood Assessments: All cognitive and mood assessments will be collected on a laptop, tablet device, or by paper and pencil. You will perform a standardized cognitive battery that will assess your vigilance, memory, reaction time, executive function, mood, risk-taking, aggression, and any environmental symptoms you may be experiencing. Mood and aggression assessments will require you to answer a series of questions. Vigilance, memory, reaction time, risk-taking, and executive function assessments will require you to respond to stimuli presented on a computer screen using a computer keyboard. These assessments will take approximately 90 minutes to complete and will be conducted four times during each testing cycle. You will be permitted to take 1-2 minute breaks between tasks. You will also be trained on these tests prior to beginning the first testing cycle. A brief cognitive battery will also be performed throughout the physical performance assessments. This assessment will determine your feelings, arousal,

perceived exertion, response inhibition, working memory, and cognitive flexibility. This assessment will take approximately 15 minutes.

Physical Performance Assessments: You will perform physical assessments to determine your exercise tolerance, muscular strength and dexterity. Exercise tolerance will be assessed on a cycle ergometer where you will pedal at a moderate intensity for approximately 15 minutes while completing a brief cognitive battery. You will also perform an assessment of your grip strength where you will squeeze a hand-held device as hard as you can. This assessment will be competed for both hands. Finally, you will perform a manual dexterity test on a computer or tablet device. These assessments will take approximately 45 minutes and be completed four times during each testing cycle. You will be trained on these tests prior to beginning the first testing cycle.

HOW LONG WILL I BE IN THE STUDY?

The study will last 12 days, with 4 days of the cognitive, mood, and physical-performance testing throughout the days and nights.

WHAT PRECAUTIONS DO I NEED TO TAKE?

You must not drink alcohol, consume caffeine or any other substance (like nicotine) that will alter your alertness, performance, or heat/cold tolerance within 24 hours of each test day. You must also refrain from vigorous physical activity 24 hours prior to testing. You must consume the meals included in the study diet and abstain from over-the-counter medications, unless otherwise permitted by our medical team. Lastly, you must refrain from dietary supplement use within one week of initial screening and at any time while enrolled in the study. If you regularly take a multi-vitamin, containing up to 100% RDA, you may continue use throughout the study.

HOW MANY PEOPLE WILL BE IN THE STUDY?

A total of 16 participants are needed to complete this study. We require that at least 16 volunteers complete the study to account for dropouts. All screening/testing will stop once complete data has been collected on 16 participants. We will recruit a maximum of 60 volunteers. Though you may be eligible and want to participate, if we are able to finish data collection on 16 participants before you are scheduled to begin testing, your participation in the study may be terminated.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Source of Risk or Discomfort:	Risk or Discomfort:	How We Minimize Risk or Discomfort:
Modafinil Medication	The most common side effects of modafinil are headache, nausea, nervousness, stuffy nose, diarrhea, back pain, anxiety, trouble sleeping, dizziness, and upset stomach. Rare but possible serious side effects include: a serious rash or a serious allergic reaction (i.e., skin rash, hives, sores in mouth or skin blisters and peels, swelling of face, eyes, lips, tongue, or	• We are recruiting healthy individuals with no known health problems that could increase the risk of side effects. • Individuals taking drugs known to interact with modafinil (such as methylphenidate, dextroamphetamine, clomipramine, MAO inhibitors, warfarin, ethinyl estradiol, cyclosporine, etc.) will be excluded from the study. • Individuals with a current or history of mental health issues will be excluded from participation if

	throat, trouble swallowing or breathing, hoarse voice), depression, anxiety, hallucinations, mania, thoughts of suicide or other mental health issues. Harm to unborn fetus is possible in pregnant females. Hormonal contraception can also have limited effectiveness up to one month after discontinuing modafinil.	determined by OMSO physician or healthcare provider to put the individual at an increased risk. • Individuals with current cardiovascular problems will be excluded from participation. • All female volunteers will complete a pregnancy test prior to each testing cycle where they may receive modafinil. Pregnant females will be excluded from participation. • Individuals on contraceptives (oral contraceptive pill, intrauterine device, contraceptive implant, contraceptive injection, etc.) will be excluded from participation. Use of condoms as a form of contraception is permitted. • Individuals with history or current abuse of alcohol or drugs will be excluded from the study. • You will be monitored continuously so that any serious adverse reaction will be immediately apparent and emergency treatment can be administered.
Cold exposure	Freezing injuries to the skin and hypothermia Cold-induced asthma, and/or Cold-induced bronchospasm	• We are using an electronic temperature pill to continuously monitor your core body temperature. As well as, utilizing skin temperature sensors on your body. • You will be provided with cold weather apparel that is intended to maintain your core body temperature and prevent freezing injuries to the skin. • You will be removed from the cold environment if your core body temperature drops too low. If warranted, medical treatment will be administered. • You also have the option of withdrawing from the study should you decide the discomfort is too great.
Sleep deprivation	Sleepiness, irritability, poor concentration, and/or digestion discomfort Impaired driving performance Potentially increases the risk of cold weather injury	• You will be monitored closely and while there are no acute, serious medical risks associated with sleep deprivation, you always have the option of withdrawing from the study should you decide the discomfort is too great. • All volunteers will be escorted back to the barracks by study personnel or be provided transport with a rideshare platform (i.e., Uber, Lyft). • You will be advised to not operate a car or machinery for 12-16 hours after your participation. • Your core and skin temperature will be monitored during the study.
Demographic information and Cognitive/mood assessments	Some questions may make you feel uncomfortable or uneasy	• All tools will only be used for research purposes and will use your subject ID versus name. • You are allowed to skip any question that you feel too uncomfortable to answer.
Exercise tolerance, and Muscular strength tests	Brief periods of moderate physical activity rarely pose risks to healthy individuals; however, you may experience lightheadedness, fatigue, cardiovascular risks, muscle strains or soreness.	• You will be closely, continuously monitored by staff members and in the unlikely event that some physical problem occurs, you be provided with immediate medical treatment.

	Mild to severe muscle soreness may continue for one to seven days.	• Only those determined healthy and passing the medical screening will participate in this study.
Core temperature pills	Capsules can cause internal injury during magnetic resonance imaging (MRI). Can be difficult to swallow or could be retained in the bowels. May cause slight discomfort upon insertion	• Volunteers will wear a medical bracelet to ensure no MRIs are conducted within 24 hours of inserting or consuming the core temperature pill. • Rectal suppository will be recommended to avoid risks of bowel retention and difficulty swallowing. • Volunteers will be excluded from the study if they have been diagnosed with obstructive gastrointestinal diseases to avoid bowel retention or report difficulty swallowing large pills. • You will be instructed by credentialed staff on how to properly insert or ingest the pill
Skin temperature	There are no known risks associated with the measurement of skin temperature other than potential skin irritation or allergic reaction to adhesives	• You will be excluded from the study if you are allergic. • We recommend washing the exposed area after testing.
Body Composition	Radiation, risk to fetus.	• Low dose of radiation, a DEXA scan is approximately 1/500 of normal annual background radiation (300 mrem/year), 1/6 of the radiation received in a transatlantic flight (3.825 mrem), or 1/3 of the radiation received in a chest X-ray (2 mrem). • Urine pregnancy tests will occur within 24 hours of the DEXA scan. Pregnant females will be excluded.

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?

There is no direct health or other benefits related to participating in this study. Information gathered from this research may benefit other people in the future.

WHAT IF UNEXPECTED INFORMATION IS LEARNED ABOUT MY HEALTH?

Any incidental or unexpected health findings identified by OMSO during the screening process or throughout the research process will be documented and disclosed to you. You will be encouraged to make an appointment with your primary care physician.

WILL RESEARCH RESULTS BE SHARED WITH ME?

Yes, we will be able to share results of your body composition, cognitive and mood tests if requested once you have completed all study procedures. After all data collection is complete, we will be able to tell you when you received placebo and modafinil. No other information will be shared.

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

The only alternative is not to participate in the study.

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

If you travel more than 50 miles to the Natick Soldier Systems Center, your transportation to and from the center will be paid for by the study. You may be reimbursed for any additional travel costs or other costs related to participation in this research.

If you are an active-duty Soldier coming to Natick to participate in research on temporary duty station (TDY) permissions, your transportation and lodging will be paid for by the study, and compensation for meals will be provided at the local per diem rate for days you are not being provided with food/snacks in the laboratory.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

Civilian volunteers who are not government employees will be compensated up to $1,440 for completing the study. If the study is not completed, compensation will be prorated based on the study activities completed at the time participation ends. The following payment schedule will be used to prorate compensation for your time: $240 for completing familiarization testing, $120 for completing baseline testing, $520 for completion of each two-day cold-stress condition ($1,040 for completing both), and $40 for completing the final recovery and washout period.

You will receive payment within approximately ten weeks of study completion. Your social security number will be needed to process your payment, as required by law. This information will be carefully protected. Total payments of more than $600 within once 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.

If you are active-duty military or a civilian volunteer who is a government employee, you will not be paid for your participation. However, military members may be eligible for hazardous duty pay for exposure to cold. We will submit a request for this but cannot guarantee they will receive it.

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:

Harris R. Lieberman, PhD
U.S. Army Research Institute of Environmental Medicine
Building 42
10 General Greene Ave
Natick, MA 01760
Phone Number: 508-206-2326
Email: harris.r.lieberman.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 believe you have sustained a research-related injury, please contact the Principal Investigator (PI) via one of the avenues specified above.

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 with an assigned research participant number that will not include your name or Social Security Number. The link between your participant number and your research records will be kept in a locked cabinet or on a password-protected computer file, and Dr. Lieberman and the study coordinators are the only people who have access. The master link will be destroyed upon study closure.

Some or all of the data you provide during this study will be de-identified and retained at USARIEM indefinitely, for either re-analysis under this research effort or under other approved, future research plans. 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 your permission or future consent to do so. If you do not wish your data to be retained for future use by any organization that is not listed, you should not participate in this study. De-identified electronic data records will be maintained for a period of at least ten years after the study has been completed.

When the results of the research are published, no information will be included that would reveal your identity to others. Specific permission to use photographs or video recordings of you and the manner in which they may be used will be requested and documented in an Audio/Visual Image Release form. If you do not sign the photo release form, every effort will be taken to ensure no photos of you will be taken, and in the event that a photo inadvertently contains your picture, it will be modified to obscure your identity. 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:

- US 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 and Compliance (ORQC)
- The Food and Drug Administration (FDA)

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 or 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 future relationships with USARIEM. You can withdraw by notifying the PI verbally or by writing. At the time of study withdrawal, you can voluntarily disclose to the PI your reason for withdrawing from study participation, however this is not required. If you choose to withdraw when in the cold chamber, you will be allowed to leave the chamber.

WHAT COULD END MY PARTICIPATION IN THE RESEARCH?

The investigator may withdraw you from participating in this research if:

- You are not willing to follow study procedures
- You become ill or injured, or to protect your health and safety

The investigator will make the decision and let you know if it is not possible for you to continue. Your taking part in the study may be stopped without your consent if it is determined by the investigator that remaining in the study might be dangerous or harmful to you or other participants. If you are withdrawn or decide to withdraw during the study, no further data will be collected from you. The data that has been collected from you up to that point may still be used for analysis.

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 new information is provided to you, the investigators will obtain your consent to continue participating in this study.

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

If you have questions about the research at any time, you should contact Harris R. Lieberman, PhD, U.S. Army Research Institute of Environmental Medicine, Building 42, 10 General Greene Ave., Natick, MA 01760. His Phone Number is: 508-206-2326. His Email address is: harris.r.lieberman.civ@health.mil

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 or USARIEM ORQC at phone (508-206-2371) or by email at usarmy.natick.medcom-usariem.mbx.usariem-rqc@health.mil

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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