

SGRD-UE-EMT (70)

12 August 1992

MEMORANDUM THRU

Director, ^{mmj} Thermal Physiology and Medicine DivisionDirector, ^{WBS} Environmental Physiology and Medicine Directorate

FOR Commander, USARIEM

SUBJECT: Request Approval for Addendum to HURC #400

1. I wish to change the Climatic conditions described in the heat acclimation phase and experimental testing phase of the HURC #400 protocol and append the approved practice session to include familiarizing the subjects with the procedures which will be used during experimental testing.

2. The approved heat acclimation protocol was to be performed in a 40°C - 20% rh environment. Unfortunately, due to environmental restrictions, the engineers cannot run the compressor in the Climatic Building. Thus, they have little ability to control the dry bulb temperature or relative humidity. However, they believe they can maintain relatively stable and reproducible conditions if the climatic conditions are set at 35°C - 75% rh. Adjusting our protocol to these new climatic conditions will raise the WBGT (31 vs 23°C), thus raising the thermal stress placed on the subjects. However, we do not believe these conditions will pose undue health risk to the subject as we will still monitor rectal temperature and heart rate. Performing the acclimation protocol in the large tropic chamber is an efficient method of acclimating a group of subjects. In contrast, we can only acclimate 2 people at a time if we use the climatic chambers within USARIEM. Therefore, we wish to heat acclimate the subjects for HURC #400 in a 35°C - 75% rh environment. In the event that the engineers cannot adequately maintain the environmental conditions ($\pm 3^\circ\text{C}$; $\pm 7\%$ rh) we will perform the acclimation protocol in the climatic chambers within USARIEM. The environmental conditions will be 35°C - 75% rh with wind speed of 1 m/sec.

3. I wish to change the climatic conditions during the experimental phase from 35°C - 20% rh (16°C WBGT) to 30°C - 50% rh (22°C WBGT). The ambient temperature needs to be reduced to 30°C because the metabolic cart used for measurement of oxygen uptake and cardiac output will not function properly when operating in environmental conditions greater than 30°C. This change will not affect the results of the experiment nor pose additional risk for the subject.

4. The approved protocol describes a practice session prior to experimental testing during which energy expenditure of each soldier will be measured at various treadmill speeds and grade

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combinations; with the goal of determining combinations which elicit 25%, 45% and 65% of each subject's maximal oxygen uptake. I wish to append the protocol to also include that we will familiarize/practice the other procedures which will be performed during experimental testing (i.e., cardiac output, esophageal temperature; local sweating rate.

Scott J. Montain

SCOTT J. MONTAIN
CPT, MS
Research Physiologist

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38; the proponent agency is OTSG.

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087

Principal Purpose: To document voluntary participation in the Clinical Investigation and Research Program. SSN and home address will be used for identification and locating purposes.

Routine Uses: The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State, and local agencies.

Disclosure: The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.

PART A — VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____ SSN _____,
having full capacity to consent and having attained my _____ birthday, do hereby volunteer to participate in Interaction of Hydration and Metabolic Intensity on Thermoregulatory Responses During Exercise-Heat Stress

(Research study)

under the direction of Captain Scott J. Montain
conducted at US Army Research Institute of Environmental Medicine, Natick, MA 01760-5007
(Name of Institution)

The implications of my voluntary participation; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights or study-related injury, I may contact
Office of Chief Counsel

at US Army Natick Research Institute of Environmental Medicine, (508) 651-4322
(Name, Address and Phone number — include Area Code)

I understand that I may at any time during the course of the study revoke my consent and withdraw from the study without further penalty or loss of benefits; however I may be required (military volunteer) or requested (civilian volunteer) to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

PART B — TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: *(Provide a detailed explanation in accordance with Appendix C, AR 40-38 or AR 70-25.)*

This study will examine your ability to work in the heat when you have less than normal body water (dehydrated). We wish to determine if dehydration has the same effect during light as moderate and high intensity work (treadmill walking and running). This study will be conducted at the U.S. Army Research Institute of Environmental Medicine (USARIEM) and the U.S. Army Natick Research, Development and Engineering Center (NATICK) facilities, Natick, MA, and at the Naval Blood Research Laboratory, Boston, MA.

Prior to experimental testing, your physical fitness and percent body fat will be determined. You will also complete an exercise session in which we will determine your energy cost to walk and run on a treadmill and practice the experimental procedures used during experimental testing. You will then complete a 4 to 12 consecutive day heat acclimation program. (This could include one or two weekends). For this you will attempt daily 2-h walks in a hot-wet (95°F, 75% rh) environment. After completing the heat acclimation program, your total body water will be measured on one day, and your blood volume will be measured on another day. You will then attempt nine Heat Stress Tests during the next five weeks. You will also complete additional heat acclimation sessions between the dehydration sessions and Heat Stress Tests; no more than two Heat Stress Tests will be conducted in one week. The tests and procedures are described below.

% Body Fat. To estimate your body fat, you will be weighed on a scale underwater while you hold your breath. The gas in your lungs will be measured by having you breathe oxygen through a snorkel-like apparatus. This procedure takes about 45 minutes.

Maximal Effort Exercise. You will first practice walking (3.5 mph) and running (6 or 7 mph) on a treadmill. For the maximal effort exercise test, you will run on the treadmill and the treadmill grade will be increased (by 2 1/2%) at 1.5-minute intervals until you can no longer continue. This test takes about 30 to 90 minutes.

Total Body Water. You will be asked to drink approximately 1 ounce of labelled water called deuterium oxide. This labelled water contains no radioactivity but is a special type that occurs normally in nature in small amounts and can be used to distinguish total body water by the measurement of deuterium oxide in your blood. Deuterium oxide containing water appears and tastes completely normal and possesses no health risk to you. However, it may cause temporary dizziness or balance problems. Blood samples will be obtained from your arm once immediately before drinking the water and once 3 hours later. The total amount of blood removed for this procedure will be less than 1/2 ounce. This test takes about 3.5 hours.

I do do not *(check one & initial)* consent to the inclusion of this form in my outpatient medical treatment record.

SIGNATURE OF VOLUNTEER		DATE	
PERMANENT ADDRESS OF VOLUNTEER		TYPED NAME OF WITNESS	
		SIGNATURE OF WITNESS	DATE

Blood Volume Measurement. This test will be performed at the Naval Blood Research Laboratory in Boston. A small sample of blood (less than one ounce) will be taken from your arm vein. Radioactive material will be added, and then it will be reinjected into your arm. You will receive a very small amount of radioactive material. The total amount of radiation that you receive is less than one chest x-ray. One half of the radioactivity will be gone from your body in 30 to 60 days. Small samples of blood removed will be about one ounce. This test will take about three hours.

Heat Stress Tests. You will attempt nine Heat Stress Tests; three with normal body water levels, three when dehydrated by 3% of body weight, and three when dehydrated by 6% of body weight. For each of these hydration conditions, the exercise work intensity will be 25%, 45% and 65% of your physical fitness level. You will not complete more than three Heat Stress Tests within a given week. You will be asked to limit your food and fluid intake for about two days before the dehydration Heat Stress Tests. The day before each Heat Stress Test, you will report at 1200 h. You will first be weighed, then you will enter a Climatic Chamber, which will be 104°F (20% humidity). In the chamber, you will rest and exercise so that you sweat. If this is the day before a normal hydration Heat Stress Test, you will be given water to fully replace your sweat. If this is the day before a dehydration Heat Stress Test, you will not be given water. For a 150-lb. man to dehydrate by 3% and 6% of body weight, he would have to lose ~2 quarts and ~4 quarts of fluid, respectively. This could take 4-6 hours. Once you have lost the desired body weight, you will go to a comfortable room and remain there until the next morning. During the night and next morning, you will be allowed to eat fresh fruit, but only in the amount that your weight allows. In the morning you will enter the chamber for the Heat Stress Test. It will be 86°F (50% humidity). You will try to perform treadmill exercise (walking or running) for 50 minutes.

During all exercise tests, you will wear shorts and tennis shoes. You will have several electrodes taped to your chest so that we can monitor your heart rate. During the Heat Stress Tests, we will measure your skin, rectal and esophageal temperatures. Also, your rectal temperature will be measured during the acclimation sessions. The rectal thermometers are flexible probes which may be somewhat unpleasant to insert the first time, but are not harmful. Before each Heat Stress Test you will place a thin plastic tube through your nose and swallow it while drinking water. This tube will measure your esophageal temperature and will remain in place throughout the experiment. There may be some discomfort during the swallowing of the esophageal probe, and you may have to gag. A plastic capsule will be taped to your arm to measure sweating. During the Heat Stress Tests (and total body water measurements) you will have a sterile plastic tube (catheter) in your arm vein so that we can take blood samples. A total of ~1 ounce of blood will be obtained during each Heat Stress Test. During the exercise tests, you will be asked to periodically breathe through a mouthpiece while wearing a noseclip. In addition, you will be asked to rebreathe a carbon dioxide-oxygen mixture for 1-20 seconds for several times during each Heat Stress Test.

Potential Risks and Hazards. The primary risks of participating in this study are those associated with (a) physical exercise; (b) high body temperature; (c) dehydration; (d) obtaining venous blood samples; (e) exposure to radioactively labelled material; (f) rebreathing carbon dioxide and the additional risks of the combinations of these. The stress of exercise, and especially maximal effort, increases the potential for uncovering and/or aggravating pre-existing heart problems. Therefore, the electrocardiogram will be displayed and periodically monitored. Muscle soreness, cramps, and general fatigue may also result from exercise; this pain and discomfort is temporary and not deemed harmful. Misjudgement or accident (i.e., falling on treadmill) can result in bodily injury during physical exercise. The risk of this is probably less during the supervised activities used in a study than in unsupervised exercise, free play or competitive sports. Also, breathing in water is a risk associated with the

Initials of Volunteer _____ Initials of Witness _____

underwater-weighing procedure.

High body temperatures are expected in the acclimation sessions and Heat Stress Tests; so body temperature will be closely monitored. During passage of the esophageal probe, injury to mucus membranes could occur if due care is not taken. There is also a remote risk of shock if there is a current leak. During the Heat Stress Test, you will be provided water to maintain the desired hydration level. Testing will be discontinued, and you will be removed to a cool environment should your rectal temperature exceed 103°F, or if the rate of temperature increase exceeds 1.1°F in five minutes. Even if the above limit has not been reached, symptoms and signs of impending heat illness, such as confusion, coordination difficulties, excessive breathing and/or faintness will result in discontinuation of testing and your removal to a cool environment. When your heart rate exceeds 180 bpm or 90% of your measured maximal value (whichever is lower), a physician will individually monitor you. When your heart rate achieves 200 bpm or 95% of your measured maximal value (whichever is lower), the experiment will be terminated. During all testing, a staff member will be stationed near you to observe and assist you should the need arise. Testing will be discontinued if you show any signs of unusual distress during the work. It is recognized that overexposure to heat may lead to heat injury, "heat exhaustion", or "heat stroke". However, under this protocol safeguard tolerance limits are placed on responses to provide a margin of safety and reduce the risk to your health.

Within the past seven years, we have conducted approximately 200 exercise-heat experiments on subjects dehydrated and experienced no serious adverse physical effects. The primary risk of hypohydration is that of the subsequent high body temperature during exercise-heat stress, and these risks have been discussed.

Needle punctures and catheterization of veins in the extremities will be performed by skilled technicians with sterile techniques. These procedures involve extremely little risk of any injury beyond possible infection, bruising and temporary discomfort. Blood volume measurements with the labelled radioactive chromium and albumin methods are performed routinely in the United States, and the low level of radiation is associated with no known risks. During the course of the entire study (approximately nine weeks), you will have a total of ~12 ounces of blood removed.

The risk associated with rebreathing 8 to 15% CO₂ (in oxygen) for 15 to 20 seconds is temporary light-headedness, and a technician will closely monitor you.

The benefits of this study to you are only indirect. You will be able to find out your percent body fat and physical fitness level. Both of these measurements are of value to individuals interested in assessing the state of their physical conditioning program. All data and medical information obtained about you as an individual will be considered privileged and held in confidence; you will not be identified in presentation of the results. Complete confidentiality cannot be promised, particularly to subjects who are military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities, and applicable regulations note "the possibility that the U.S. Army Medical Research and Development Command officials may inspect the records."

This study requires a considerable time and energy commitment from you. You will participate in experiments that will require a significant (1-6 h) amount of time on approximately 40 days over a nine week time span. Please take your commitment seriously and plan to complete all testing if you volunteer. However, you are free at any time to withdraw from the study without prejudice.

You will receive a copy of this consent form for your personal records.

Initials of Volunteer _____ Initials of Witness _____