

MCMR-UE-EMT

20 January 1995

MEMORANDUM THRU

Chief, Thermal Physiology and Medicine Division

Director, Environmental Physiology and Medicine Directorate

Commander, U.S. Army Research Institute of Environmental Medicine

SUBJECT: Addendum to re-opened HURC 400 protocol.

1. I wish to add the collection of blood sampling to the HURC 400 trials which will be conducted January 24 to February 1. The blood samples will be drawn to collect preliminary data on the effect of hypohydration on immune responsiveness and cytokine concentration. A total of 6 blood samples will be drawn via venepuncture and total volume for the blood draws will be less than 40 ml. The blood samples will be obtained before dehydration, before exercise when either eu- or 5% hypohydrated, and after 50 min of exercise. A QA'd person will perform all phlebotomy procedures.
2. The reason for the blood sampling will be explained to each volunteer. Persons not interested in blood sampling procedures will be allowed to participate in the protocol without prejudice.
3. The blood samples will be processed in LTC Shippee's laboratory as part of his laboratories efforts to develop immune and cytokine assays.
4. A revised consent form which includes in blood sampling procedures is included for your review.



SCOTT J. MONTAIN

CPT, MS

Thermal Physiology and Medicine Division

VOLUNTEER AGREEMENT AFFIDAVIT

This form complies with AR 70-25 and 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

under the direction of Scott J. Montain

conducted at US Army Research Institute of Environmental Medicine, Natick MA
(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

Contact telephone(s): 508 651-4564 CPT Scott Montain

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, Development, and Engineering Center (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.)

You are being asked to perform two additional exercise tests for the study you completed examining if dehydration has the same effects during light, moderate and high intensity work. The two additional trials are being done to determine whether the low wind speed used in the original study may have influenced the rise in body temperature and heart rate accompanying dehydration during high intensity exercise. For these exercise tests, the wind speed will be approximately 5 mph rather than 2 mph. This study will be conducted at the U.S. Army Research Institute of Environmental Medicine (USARIEM).

You are also being asked to participate in a separate experiment which will provide preliminary information regarding the effect of dehydration on your immune system. It will require blood samples to be taken when both euhydrated and after dehydration. Your participation in this aspect of the study is highly encouraged, but is not a requirement for participation.

Heat Stress Tests. You will attempt 2 Heat Stress Tests; one with normal body water levels and one when dehydrated by 5% of body weight. For each of these hydration conditions, the exercise work intensity will be 65% of your physical fitness level. Each test will be separated by approximately one week. You will be asked to limit your food and fluid intake the day prior to the dehydration Heat Stress Test. The day before each Heat Stress Test, you will report to the laboratory. 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 5% of body weight, he would have to lose ~3.5 quarts of fluid. This could take 4-5 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 the 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 dehydration 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. During the exercise tests, you will be asked to periodically breathe through a mouthpiece while wearing a noseclip.

Blood Sampling. Blood samples will be obtained from an arm vein before dehydration, before exercise when either normally hydrated or dehydrated, and after 50 minutes of exercise. Approximately 1 tsp of blood will be removed each blood draw; less than 8 tsp will be taken during the study.

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

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) blood sampling; and the additional risks of the combinations of these. The stress of exercise 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. Misjudgment 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.

High body temperatures are expected in the dehydration 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 of veins in the extremities will be preformed by skilled technicians with sterile techniques. These procedures involve little risk of injury beyond possible infection, bruising and temporary discomfort.

There are no direct benefits to you for participation in this study. 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 Materiel Command officials may inspect the records." Information on the USAMRDC Form 60-R will be stored at the U.S. Army Medical Research and Materiel Command for future notification purposes should new information become available concerning your participation in this study.

This study requires a considerable time and energy commitment from you. 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.

Witness's initials	Volunteer's initials
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