

SGRD-UE-MEP (70)

19 January 1989

MEMORANDUM THRU: ~~CHIEF, PHYSIOL BR, MIL ERG DIV~~
~~DIR, MIL ERG DIV~~

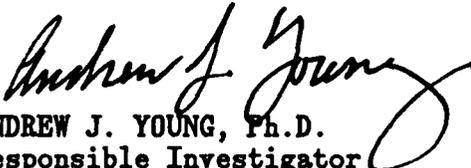
MMS
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FOR: COMMANDER, USARTEM

SUBJECT: Addendum to Protocol

1. Experimental testing has begun for the protocol, "Role of Thermal Factors for Metabolic Adaptations to Physical Training" (HURC #344).
2. The objective of this project is to compare the responses of subjects exercising in environmental conditions which prevent a rise in body temperatures to those of subjects exercising in environmental conditions exacerbating changes in body temperatures. For the former condition, 20°C water was employed. This has been found effective during initial testing. For the latter condition, 30°C water was employed. Initial testing indicates this temperature is too low to elicit significantly greater rises in body temperature than in 20°C water.
3. It is requested that a change in the experimental conditions be permitted so that testing and training be performed in 35°C rather than 30°C water.
4. The consent form has been revised (attached) to reflect this change. Subjects will be briefed on the modification and requested to sign the modified consent form.
5. This modification does not alter the risks of injury for the subject, as all physiological criterion for terminating testing remain the same as stated in the original protocol and in the Type Protocol. In addition, the 30°C water will elicit only the thermal strain we had anticipated for the 30°C water.
6. It should be noted that six subjects will be asked to repeat one experimental trial (i.e., the submaximal exercise test in warm water) if this change is approved.

Encl


ANDREW J. YOUNG, Ph.D.
Responsible Investigator

VOLUNTEER AGREEMENT AFFIDAVIT

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

PRIVACY ACT OF 1974

Authority: 16 USC 2613, 44 USC 2101, and 16 USC 1671-1687.

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

Routine Uses: The SSN and home address will be used for identification and testing 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(1) - VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-26 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/give consent as legal representative for _____ to participate in _____

The Role of Thermal Factors for Metabolic Adaptations to Physical Training
(Research study)

under the direction of Andrew J. Young, Ph.D.

conducted at U.S. Army Research Institute of Environmental Medicine, Natick, MA 01760-5007

(Name of Institution)

The implications of my voluntary participation/consent as legal representative; 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): 508-651-4837

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/the rights of the person I represent on 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 of Hospital (Include Area Code))

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

PART A (2) - ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD)

I, _____, SSN _____, having full

capacity to consent and having attained my _____ birthday, do hereby volunteer for _____ to participate in _____

(Research Study)

under the direction of _____

conducted at _____

(Name of Institution)

Continue on Reverse

PART A(2) - ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD) (Cont'd)

The implications of my voluntary participation; the nature, 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 I may contact

at

(Name, Address, and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my assent and withdraw from the study without further penalty or loss of benefits; however, I may be requested to undergo certain examination 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 E, AR 49-58 or AR 79-56.)

This investigation will study the effects of changes in your body temperature on your responses to exercise and physical training. Normally, body temperatures rise during exercise. We want to determine if responses to exercise are different when we prevent this rise in body temperature. It is hoped that this research will help to develop improved physical training programs and predict the effects cold and heat on ability to work and exercise.

Most of the tests will be performed at USARIEM, in Natick, Ma. However, on four occasions testing will be conducted at the Naval Blood Research Laboratory located in Boston, Ma. This study will require sixteen consecutive weeks of tests and physical training. The time required for each procedure varies, but generally you will be required for three hours per day, Monday through Friday. The tests that you will complete are described below.

1. During the first week, we will measure your initial level of physical fitness and body composition. You will also practice the exercise that you will be performing.

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

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (if volunteer is a minor)
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

Maximal Cycling Exercise Test. This test takes about one hour on three days. Each day you will perform three 5 minute exercise bouts on a cycle ergometer with 25 minute rest between bouts. Each bout will require more effort to complete than the previous one until your maximum capability is achieved. While you cycle, you will breathe through a mouthpiece connected to a machine which measures how much oxygen you are using. Also, you will have electrodes taped to your chest to monitor your heart rate. Exercise, especially maximal exercise, may uncover or aggravate a pre-existing heart disorder, therefore you will be carefully monitored any sign of this while you exercise. Healthy young men are unlikely to experience any serious problems with this test. You may experience muscle soreness and fatigue and some people experience cramps and nausea during this test. These symptoms are temporary and not harmful. You could fall off the ergometer and become injured so a "spotter" will be near you to provide assistance.

Body Composition. These measurements take about two hours on one day. To estimate the percentage of your weight that is fat, you will be weighed on a scale underwater while you hold your breath (the water in the tank will be warm). The gas in your lungs will be measured by having you breathe oxygen through a snorkel-like apparatus. You could accidentally inhale some water during this test, so an assistant will be stationed close to help you if needed. In a separate procedure, the thickness of fat at several sites under your skin will be measured using calipers which lightly pinch a fold of your skin. Next, the size of your leg will be measured by having you immerse your leg in a tub of warm water. None of these measures causes any discomfort.

Exercise Familiarization. Most of the exercise in this study will be done on a special cycle-ergometer while you are immersed in water. You will complete three 10 minute familiarization rides on each of three days. These rides will vary in intensity from easy to hard. During the rides, we will measure your heart rate and how much oxygen you are using as described above, and your rectal temperature will be measured using a flexible probe which, although somewhat unpleasant to insert the first time, is not harmful. The hazards of exercise are the same as for the maximal tests, however, it is less likely that you would experience adverse effects since you will be exercising below your maximum capacity. Since you are exercising in the water, you could inhale water, but your head will be above water at all times, and someone will be stationed close to you to provide assistance if needed. Because you will be in the water, you will be grounded and therefore there exists the potential for electrical shock. However, you will not be connected to any high voltage circuits, and the pool will be closely checked for safety hazards to reduce the chance of you experiencing a shock.

2. During the second week, you will complete three experimental tests.

Submaximal Exercise Test. You will complete two of these tests during this week, and the tests will be separated by a 48 hour rest period. The two tests will be identical with one exception: during one test you will be exercising in cool (68°F) while in the other you will be exercising in warm (95°F) water.

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PART B - TO BE COMPLETED BY INVESTIGATOR (cont'd)

First, your nude weight will be measured, and electrodes and sensors will be taped on your skin to allow your heart rate, skin temperature and the activity of your muscles to be monitored. You will also insert the rectal probe. A sterile plastic catheter will be placed in a vein on your arm to enable blood samples to be obtained. The catheter is sometimes uncomfortable to put into the vein, but once in place it usually causes no pain. Next, a small sample of your thigh muscle will be obtained by a procedure called a biopsy. The top of your thigh will be shaved and cleaned, and local anaesthetic (Xylocaine, 2%) will be injected into the skin to prevent pain. A small (~1cm) cut is made in your skin. A special needle is inserted through the cut and a small piece of muscle is obtained. The needle remains in the muscle for about five seconds. Afterwards, a bandage and a waterproof patch will be placed over the wound. The biopsy procedure can be uncomfortable although your ability to exercise will not be impaired.

After the biopsy, you will sit on the cycle-ergometer which is supported on a platform above the immersion tank. Following a 20 minute rest period, a blood sample (about a tablespoon) will be collected. A small (23 gauge) needle with a temperature sensor inside will be inserted into a muscle on the back of your arm and the top of the thigh opposite the one on which the biopsy was performed. This may sting at first, but discomfort should quickly pass. The needle will remain in place during exercise to allow muscle temperature to be measured. You will be lowered into the water, and exercise at 75% of your maximum capability for exactly 60 minutes. Periodically, the amount of oxygen you are using will be measured. Several times you will breathe in and out of a bag containing carbon dioxide for about five breaths. This procedure, which is both painless and harmless, is part of a test to determine how much blood your heart is pumping. We will collect blood samples five times during exercise. The total amount of blood taken from you during this experiment will be about 5 tablespoons (78 ml). After you have completed the exercise, you will leave the water, and a final sample of your thigh muscle will be obtained. It will not be necessary to make a new cut in your skin. The biopsy will be done through the original cut which will not have had time to seal closed. When this is completed, the cut will be closed with a special seal that minimizes scar formation, and then a bandage is placed over the wound.

There are some hazards associated with this experiment. To ensure your safety, the experiment will be stopped if your rectal temperature falls below 95°F or rises above 103.1°F. The experiment will also be stopped if your heart rate exceeds 180 b·min⁻¹ for more than five minutes. Both the catheterization and the biopsy can result in bruising and soreness which can persist for a day or two. These are not usually serious or uncomfortable enough to limit normal activity, and they resolve without treatment. The catheterization site, biopsy site or the site at which the muscle temperature probes are inserted could become infected. To prevent this, the sites will be covered with waterproof patches during immersion and carefully bandaged after the experiment. You will be instructed on how to care for the wounds and checked to ensure the wound heals satisfactorily. The pool will be rigorously cleaned, filtered and appropriate levels of chlorine maintained to ensure that it does not pose a health hazard.

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Blood Volume Measurement. This test will be performed at the Naval Blood Research Laboratory in Boston, and requires four hours. A sample of blood (less than a tablespoon) will be taken from your arm. Small amounts of radioactive chromium and iodine will be added to this blood, and it will be reinjected into your arm. Samples of blood will be taken during the next several hours. (This test will be repeated four times over 16 weeks and you will receive a total of 2.0 microcurries of radioactive iodine labelled albumin and 56 microcurries of radioactive disodium chromate. The amounts of radioactive materials to be administered during this study are less than the maximum amounts allowed by the Food and Drug Administration.)

3. For the next eight weeks, you will exercise in the water for 60 minutes each day, Monday through Friday. Missed sessions will be made up on the weekends. As your physical fitness improves, the intensity of exercise will be increased. During exercise, your heart rate, rectal temperature and oxygen consumption will be measured. During this part of the program, some subjects will be exercising in warm water and some in cold water. You will have no choice regarding the water temperature in which you train. This will be determined randomly and no changes will be permitted.

On Friday of every other week, a small (less than a tablespoon) blood sample will be collected before you begin exercise, using a procedure called venepuncture in which a hypodermic needle is inserted into an arm vein. The hazards of this procedure are similar to those of catheterization, but less likely. During the fourth and eighth week of training, the maximal tests will be repeated, and the blood volume measurements will be repeated during the fourth week of training. The body composition measurements will be repeated during the eighth week. These tests will all be scheduled so that they do not interfere with your regular training.

4. During the week following the eighth week of training, the two submaximal exercise tests (including the biopsy procedure) and the blood volume measurements experiments will be repeated.

5. After the experimental measurement week, you will resume training for four more weeks, but now all subjects will exercise in warm water. Resting blood samples (less than a tablespoon) will be collected on Friday of every other week, and the maximal tests and body composition tests will be repeated during the last week of training.

6. During the week following the twelfth week of training, the two submaximal exercise tests (including the biopsy procedure) and the blood volume measurements experiments will be repeated.

Throughout this study you must abide by certain restrictions. You will not begin any new physical training program and you will not engage in any strenuous activities without consulting with the principal investigator. You will refrain from smoking for at least three hours before any test or training session. You will consume no alcohol for twenty four hours before any test or exercise-training session. Finally, you will not consume food or any beverage other than water for four hours before the submaximal tests.

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You may withdraw from this study at any time without fear of prejudicial consequences. You may discontinue any exercise or test procedure at any time. A physician will be present or readily available during all testing. All data and medical information obtained about you as an individual will be considered privileged and held in confidence; you will not be personally identified in any presentation of the results of this study. However, complete confidentiality cannot be promised, particularly to subjects who are military personnel, because information bearing on your health may be required to be reported appropriate medical or command authorities, and applicable regulation notes "the possibility that the Food and Drug Administration and U.S. Army Medical Research and Development Command officials may inspect the records." Participation as a test subject in this study may provide you with limited direct benefit. Much of the testing will give you an estimate of your physical fitness, and one of the experimental aims of the study is to increase your physical fitness for endurance-type activities. At any time during this study, the investigators will answer your questions regarding information collect about you or any of the scientific aspects of the tests and procedures. You will be provided with a copy of this consent form and a detailed schedule of tests and procedures that you will be performing.

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