



The
University
Hospital

Department of Surgery
Lowell, MA 01854

Lowell, MA 01854
Tel: 603/886-1000

July 16, 1990

Michael Sawka, Ph.D.
Military Ergonomics Division
U.S.A.R.I.E.M.
Kansas Street
Natick, MA 01760-5007

Dear Mike:

I added your new protocol entitled "Reaction of hydration and metabolic intensity on thermal regulation responses during exercise heat stress" to an older protocol as we discussed. Our IRB approved the amendment. There is a new informed consent with the proper title, "Interaction of hydration and metabolic intensity on thermal regulation responses during exercise heat stress". I hope that this is sufficient for your IRB. If it isn't I can get our IRB to redraft the letter using the right words.

Hope things are going well you and you are having a pleasant summer.

Sincerely,

Richard C. Dennis, M.D.

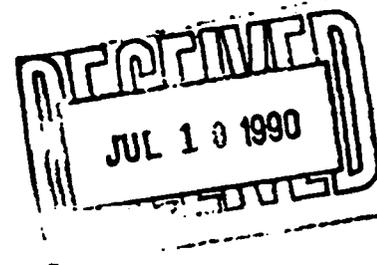
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The
University
Hospital

55117 North Street
Boston, Massachusetts 02118
(617) 782-1000



Richard Dennis, M.D.
Critical Care Medicine
A 2

July 6, 1990

RE: Protocol 2147

Dear Doctor Dennis:

Your request for an amendment to your research project, entitled Interaction of Aerobic Fitness and the Hypohydration Response During Exercise-Heat Stress, referenced above, was reviewed by the Institutional Review Board for Human Research.

I am pleased to inform you that this request has been approved by the board.

Please note, however, that this will not effect your renewal date. This project is currently approved through 9/30/90.

Enclosed you will find a validated consent form which shows the date through which it will be in effect. It is mandatory that you remove from your files any and all non-valid forms and use the enclosed as an original for the purpose of reproduction.

If you have any questions regarding this, please do not hesitate to contact me at extension 7207.

Sincerely,

Linda L. Frattura
Administrative Coordinator
I.R.B.



The
University
Hospital

13

Division of Surgery

88 East Newton Street
Boston, Massachusetts
02118

Richard J. Dennis, M.D., F.R.C.S.
Associate Professor of Surgery
and Anesthesiology
Chief, Section of
Orthopedic Medicine
1978-1989

June 26, 1990

Linda L. Frattura
Administrative Coordinator
Institutional Review Board for Human Research
Boston University Medical Center
88 East Newton Street
Boston, MA 02118

Re: Protocol 2147

Dear Miss Frattura:

I wish to amend the research protocol entitled "Interaction of Aerobic Fitness and the Hypohydration Response During Exercise-Heat Stress" (2147). This is a collaborative study between the Naval Blood Research Laboratory and the U.S. Army Research Institute of Environmental Medicine (USARIEM) at Natick. We have collaborated on four occasions with this group (IRB 1459, IRB 1459-Modification February 28, 1987, IRB 2147, and IRB 2385) and have encountered no problems. As in the original protocol, the recruitment of volunteers and all initial screening as well as the exercise testing, will be done at Natick.

The modification is entitled "Interaction of Hydration and Metabolic Intensity on Thermal Regulatory Responses During Exercise Heat Stress". The study outline of this amendment is similar to the original protocol in that the subjects are healthy male soldier volunteers who are recruited at Natick. The exercise program, Heat Acclimation, and Heat Stress Test are similar, only the details are different including a different temperature and different degrees of hypohydration and different levels of exercise.

Volunteers will come to the Naval Blood Research Laboratory and will have plasma and red cell volumes measured on one occasion exactly as in the original protocol. Our part of the study is in no way different from the original protocol. I have modified our the first paragraph and title of the informed consent to describe the different exercise program. Subjects will sign a separate Informed Consent Form at Natick describing the exercise testing and great detail.

The USARIEM has submitted this protocol to its Institutional Review Board and the program has been approved. In order to do the study their IRB requires an amendment from the Boston University IRB. Although the NBRL part is identical to the original, the design of the study from Natick's point of view is slightly different.

Thank you for your consideration.

Sincerely,



Richard C. Dennis, M.D.
Principle Investigator

encl. Informed Consent Form
Natick IRB Submission and Approval

/ams

STATEMENT OF INFORMED CONSENTINTERACTION OF HYDRATION AND METABOLIC INTENSITY ON THERMAL
REGULATORY RESPONSES DURING EXERCISE-HEAT STRESS

SUMMARY: You are being asked to participate in a research project to 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 USARIEM facilities located in Natick, Massachusetts, and at the Naval Blood Research Laboratory in Boston, Massachusetts. Details of the heat exercise testing have been explained to you in a separate informed consent. The volume of plasma and red cells contained in your body will be measured on one occasion using a small amount of radioactive chromium and radioactive iodine. These measurements will help determine your level of hydration.

PROCEDURE: We will collect about 1 ounce of your blood which will be anticoagulated using a standard solution and labeled by adding a small amount of radioactive chromium to the blood. About 2 teaspoons of this sample and a small amount of radioactive iodine will be injected into your vein. You will receive 0.5 microcuries of radioactive 125 Iodine-labeled albumin, and 5 microcuries of radioactive 51 Cr disodium chromate. Blood samples will be collected prior to the injection and up to 60 minutes after the injection. The total amount of blood collected will be less than about 2 ounces. The procedure described above is performed routinely in our laboratory. These measurements will take less than 2 hours and will be done at the Naval Blood Research Laboratory.

POTENTIAL RISKS AND HAZARDS: There is a remote chance that you might mistakenly be injected with another donor's blood and that this might possibly cause a reaction or disease (such as hepatitis), but a strict identification system virtually excludes this possibility. You could get a black and blue mark at the site of the IV, or an infection. There is also a slight risk that the radioactive iodine might cause a reaction. There are no risks known to be associated with the amounts of radioactivity that you will be exposed to in this study. The thyroid, the single organ subjected to the largest amount of 125 Iodine radiation during this study, receives less than 1/5 of the permissible exposure for a single study as outlined by the Food and Drug Administration. The radiation dose to the body is less than that of one chest x-ray.

BENEFITS: Personal satisfaction aside, you will derive no health or other benefits from your participation in this study. If you have any questions regarding the research or your participation in it, either now or at any time in the future, please feel free to ask the research team, particularly Dr. Dennis, who may be reached at 638-4950, will be happy to answer any questions you

1RB 7/6/90

may have. You may obtain further information about your rights as a research subject by calling the Institutional Review Board for Human Research at Boston University Medical Center at 638-7266. If any problems arise as a result of your participation in this study, including research related injuries, please call the principal investigator, Dr. Dennis, or Dr. Valeri at 638-4950 immediately.

VOLUNTEER SUBJECT CONSENT

I have read and understand the above explanation and the risks of participating in this study. Details of this procedure and potential risks and hazards have been verbally explained to me and I have had a chance to ask questions which have been answered to my satisfaction. I understand that any new information developed during the course of the research that may relate to my willingness to continue participation will be provided to me. I understand that my blood will be injected back to me after it has been manipulated in the laboratory and that I am asked to provide blood samples after the injection. However, I may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled. I further understand that my identity will be known only to the investigators and I will not be identified by name in any publication resulting from this study. However, the Food and Drug Administration may inspect my record. I authorize the attending physician, his assistants or designees to perform such therapies or procedures which in his professional judgement may become necessary to safeguard my health during this study.

I understand that in the event injury occurs resulting from this research procedure, medical treatment will be available at University Hospital. However, no special arrangements will be made for compensation or for payment for treatment solely because of my participation in this experiment. I understand that this paragraph is a statement of University Hospital's policy and does not waive any of my legal rights.

I understand that I will receive a copy of this form.

Signature of Witness

Signature of Volunteer

Signature of Investigator

Date

Valid for use through: 9/30/90

Per IRB: LF 7/6/90



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Division of Surgery
88 East Newton Street
Boston, Massachusetts
02118

Richard C. Dennis, M.D., F.R.C.S.
Associate Professor of Surgery
and Anesthesiology
Chief Section in
Critical Care Medicine
02118-5406

June 26, 1990

Linda L. Frattura
Administrative Coordinator
Institutional Review Board for Human Research
Boston University Medical Center
88 East Newton Street
Boston, MA 02118

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Signature of Volunteer

Signature of Investigator

Date

Valid for use through: _____

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